

**MEDICAL AND PUBLIC HEALTH PREPAREDNESS  
AND RESPONSE: ARE WE READY FOR FUTURE  
THREATS?**

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**HEARING**  
OF THE  
**COMMITTEE ON HEALTH, EDUCATION,  
LABOR, AND PENSIONS**  
**UNITED STATES SENATE**  
**ONE HUNDRED FOURTEENTH CONGRESS**  
FIRST SESSION  
ON  
EXAMINING MEDICAL AND PUBLIC HEALTH PREPAREDNESS AND  
RESPONSE, FOCUSING ON FUTURE THREATS

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FEBRUARY 26, 2015

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# C O N T E N T S

## STATEMENTS

THURSDAY, FEBRUARY 26, 2015

Page

### COMMITTEE MEMBERS

Burr, Hon. Richard, a U.S. Senator from the State of North Carolina .....	1
Murray, Hon. Patty, a U.S. Senator from the State of Washington .....	3
Alexander, Hon. Lamar, Chairman, Committee on Health, Education, Labor, and Pensions, opening statement .....	4
Casey, Hon. Robert P., Jr., a U.S. Senator from the State of Pennsylvania .....	4
Warren, Hon. Elizabeth, a U.S. Senator from the State of Massachusetts .....	32
Cassidy, Hon. Bill, M.D., a U.S. Senator from the State of Louisiana .....	34
Whitehouse, Hon. Sheldon, a U.S. Senator from the State of Rhode Island .....	45

### WITNESSES

Lurie, Nicole, M.D., MSPH, Assistant Secretary for Preparedness and Re- sponse, U.S. Department of Health and Human Services, Washington, DC ..	6
Prepared statement .....	8
Robinson, Robin A., Ph.D., Director, Biomedical Advanced Research and De- velopment Authority, Deputy Assistant Secretary for Preparedness and Re- sponse, Washington, DC .....	11
Prepared statement .....	13
Redd, Stephen C., RADM, M.D., Director, Office of Public Health Prepared- ness and Response, Centers for Disease Control and Prevention, Atlanta, GA .....	17
Prepared statement .....	18
Borio, Luciana, M.D., Assistant Commissioner for Counterterrorism Policy, Director of the Office of Counterterrorism and Emerging Threats, Deputy Chief Scientist (Acting), U.S. Food and Drug Administration, Silver Spring, MD .....	21
Prepared statement .....	23

### ADDITIONAL MATERIAL

Statements, articles, publications, letters, etc.:	
Response by Nicole Lurie, M.D., MSPH, to questions of:	
Senator Alexander .....	48
Senator Burr .....	51
Senator Isakson .....	55
Senator Kirk .....	56
Senator Scott .....	56
Senator Roberts .....	58
Senator Murray .....	59
Senator Mikulski .....	60
Senator Casey .....	62
Senator Franken .....	64
Senator Baldwin .....	65
Senator Warren .....	66



## **MEDICAL AND PUBLIC HEALTH PREPAREDNESS AND RESPONSE: ARE WE READY FOR FUTURE THREATS?**

**THURSDAY, FEBRUARY 26, 2015**

U.S. SENATE,  
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,  
*Washington, DC.*

The committee met, pursuant to notice, at 10:05 a.m., in room SD-430, Dirksen Senate Office Building, Hon. Richard Burr presiding.

Present: Senators Burr, Alexander, Cassidy, Casey, Murray, Franken, Whitehouse, and Warren.

### **OPENING STATEMENT OF SENATOR BURR**

Senator BURR. The Senate Committee on Health, Education, Labor, and Pensions will come to order. I'm delighted to steal the gavel this morning from the chair, and I apologize to my colleagues. I clearly was the only one that had people that were late for their appointments this morning, so it threw me back about 5 minutes. I apologize to our witnesses.

I thank the chairman and Ranking Member Murray, and I want to thank my good friend, Bob Casey, for his willingness to work with me on this hearing, as well as a number of other initiatives that he and I have joined together on. Once we've made some opening statements, I'll have an opportunity to introduce formally our witnesses today.

I'm pleased to have the opportunity to chair today's hearing on such an important topic that is a key aspect of our national security. Our work to strengthen our Nation's medical and public health preparedness and response has always been bipartisan. It's fitting that Senator Casey, who has been a strong partner on these issues over the years, is serving as the Ranking Member of today's hearing.

The American people expect us to do all that we can do to protect them from the full range of threats that we face, whether they're naturally occurring, as we've seen with the emergence of novel influenza strains, or are deliberate man-made attacks. Regardless of the source of these threats, we must be well-prepared to respond and to protect the American people.

In the aftermath of Katrina, Congress, through the Pandemic and All Hazards Preparedness Act, established the position of the Assistant Secretary for Preparedness and Response. The ASPR position was created to clearly answer the question of who is in

charge during a public health emergency. The statute is clear, and there should be no confusion at this point.

We need to examine why, in the midst of the Ebola response, there was uncertainty at this point. This was exactly one of the issues that we were trying to avoid by speaking clearly to who was in charge in PAHPA and strengthening the role of the ASPR in the 2013 reauthorization of the law.

Today's hearing asks a very simple but critical question: Are we ready for future threats? Our recent experience with Ebola suggests that there's still room for improvement to make sure that we're as prepared as possible. Our healthcare system was not fully stressed in those response efforts.

As with each public health emergency before, we must apply what we've learned from our response to Ebola to strengthen our overall medical and public health preparedness and response efforts so that we are better prepared for the next threat we face. We cannot put off taking the steps that we must today to be better prepared tomorrow.

We need consistent and strong leadership and support at all levels in carrying out our medical and public health preparedness and response efforts. There must be a daily focus and urgency to this work, not just when we're in the midst of responding to a crisis at hand. These efforts must be prioritized. That is how we ensure that we're better prepared to respond to the full range of threats we may face.

Ebola underscores the importance of having medical countermeasures as part of our response arsenal. Today, the Biomedical Advanced Research and Development Authority not only manages the BioShield Special Reserve Fund, our medical countermeasure procurement fund, but BARDA is also actively helping innovators bridge the advanced research and development Valley of Death to bring forward innovative medical products and platform technologies that will play a critical role in protecting the American people.

While these efforts have resulted in the development, approval, and stockpiling of medical countermeasures that we didn't have a decade ago, we know that we cannot let up on these efforts because there's much work left to be done. We still do not have any vaccines or therapeutics for some of the most serious identified threats. We must be prepared for what we have already identified while also having the capabilities to quickly pivot and execute the development of vaccines and treatments for novel and emerging threats.

The ASPR, BARDA, FDA, and CDC are all before the committee today because of the critical coordination that must occur between each of these agencies in bringing forward medical countermeasures to the strategic national stockpile as well as the coordination between all facets of our medical and public health preparedness and response efforts, including critical partnerships with States and local public health officials and our Nation's healthcare providers. Their efforts together with the important work of the National Institutes of Health is critical for ensuring that we are as prepared as possible.

There's been improvement in the coordination across these agencies. We must ensure that these efforts are as timely and seamless as possible. I look forward to hearing from our witnesses today on what is working well, where there are still areas for improvement, and how Congress and the Administration can work together to ensure that we are as prepared as possible for the future threats we face.

Almost 2 years ago, Congress passed with overwhelming bipartisan support the Pandemic and All Hazards Preparedness Reauthorization Act, legislation I authored with my colleagues on this committee and which the President signed into law.

Today's hearing provides a good opportunity to look at the aspects of PAHPA that have not gotten as much attention in recent months and years but are very important. I want to take this opportunity to underscore that each provision of the law was very carefully and intentionally crafted the way that it was.

While the administration has leveraged some provisions in the law, such as the FDA utilizing the authorized use authorities to more quickly respond to H7N9 and MERS and Ebola, including an authorization on another Ebola diagnostic just this week, other requirements remain outstanding. The deliverables required by PAHPA are not optional.

Unfortunately, it took moving forward with this hearing for a long awaited 5-year medical countermeasure budget plan and the latest strategy and implementation plan to be sent to Congress. If it's going to take the scheduling of regular oversight hearings to ensure timely action and response in these areas, then that's something that I am more than happy to chair on behalf of you, Chairman Alexander, because the urgency of this work cannot be overstated.

Our actions and inactions in this area impact the health of the American people and our Nation's overall security. Medical and public health preparedness and response is a matter of national security.

I want to thank each of our witnesses for being here today, for taking the time to be here, for the efforts that you put into your work, and for your expertise. I look forward to the hearing and to your thoughts on how we ensure that we're prepared for the future threats.

I will recognize Senator Casey.

Senator CASEY. I will yield to my senior member.

#### OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Let me just say quickly that I really want to thank you, Senator Burr and Senator Casey, for spearheading this conversation. I really appreciate all of our witnesses who are here today.

As we heard, 2 years ago, the President signed the Pandemic and All-Hazards Preparedness Reauthorization Act into law, and it was a very important step forward in terms of advancing our national health preparedness, from providing support for States and local communities facing public health emergencies to promoting a very robust pipeline of medical countermeasures including drugs and vaccines that help us combat threats to public health.

I'm really pleased that today, we have an opportunity to look to the lessons learned over the past few years and talk about what we need to do going forward to prevent and, when necessary, respond quickly and effectively to public health emergencies. As events like the Ebola cases last fall and the difficult flu season we've had made clear, this is a very important time for a discussion about protecting communities' health and having effective systems in place when risks do emerge.

I want to thank all of our witnesses who are here today. I'm very delighted that Senator Casey is running this committee for us on this side and is going to do a great job on these and many issues, and I want to thank him for that. I just want to let the committee know that I have several hearings today, including one in the V.A. that's very important on our budget. Senator Casey is taking the lead on our side today, and I will turn it over to him.

Senator CASEY. Senator Alexander, do you want to go next?

#### STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. Thank you, Senator Casey. I'll just reiterate what Senator Murray said. This committee has a long reputation for bipartisan commitment to ensuring that our country is prepared for any and all threats.

Senator Burr has been a real leader in that. He was the author of the Pandemic and All-Hazards Preparedness Act of 2006 and its 2013 reauthorization, which is why I asked him to chair this hearing. He and Senator Casey have worked together very effectively, and I thank both of them for their leadership.

I look forward to being a part of the hearing today and to continuing with whatever oversight is necessary to make sure that we do our job.

Thank you, Senator Casey.

#### STATEMENT OF SENATOR CASEY

Senator CASEY. Mr. Chairman, thank you, and I want to thank Ranking Member Murray for this opportunity, and I certainly want to commend and salute the work of Senator Burr on these issues over many years in our working together. I'll be brief because I want to get to our witnesses.

I do want to say a word of thanks to our witnesses for your testimony, for your presence here today, for the expertise that you bring to bear on these issues, and, of course, for your public service.

We've convened today, not just a panel of witnesses but a panel of expert witnesses to examine the progress we've made since the passage of the Pandemic All Hazards Preparedness Reauthorization Act known as PAHPRA. I'll try to call it the Preparedness Act so we don't get too caught up in a lot of acronyms; I wonder if people listening are always following them. I'll call it the Preparedness Act to make it easier.

As we look ahead to challenges that confront the country, at the same time we have to learn from experience that we've derived over the last decade. I think it's safe to say that we cannot hope to adequately be prepared for medical or public health emergencies if we lurch from crisis to crisis, piecing and patching together a re-



sponse when we're already in the middle of an emergency. I think we all agree on that.

Public health preparedness requires a sustained commitment and investment at the Federal, State, and, indeed, at the local level as well. We should also acknowledge that public health preparedness does not exist in a vacuum separate from the rest of our public health and medical infrastructure.

The healthcare providers and hospitals that provide care for us and the public officials working with us to keep us safe are the same ones who would be providing care for us and working to respond in the case of a public health emergency. Ensuring a basic level of access to care and supporting efforts that help Americans be healthier every day will also help us to be more resilient in the face of a pandemic, a natural disaster, or a terrorist attack.

The public health challenges our Nation must prepare for are considerable and diverse, as we've seen. In only the last several months, we've seen concerns about antibiotic-resistant superbugs, Ebola, and a worse than usual flu season.

The Preparedness Act is a framework for our medical and public health preparedness infrastructure which addresses the need for a coordinated response from multiple Federal agencies and also State and local governments as well as community partners. The law also recognizes and addresses the challenges in developing medical countermeasures and ensuring we are able to deploy those resources as needed.

With our witnesses here today, I hope to learn more about the progress we've made, and there has been lots to be positive about. We also have to make sure we're checking and ensuring that that progress continues. We must ensure our Nation is prepared for all medical and public health threats.

I want to thank Chairman Burr for this hearing.

Senator BURR. Thank you, Senator Casey.

At this time, I'd like to introduce our witnesses and welcome them. First is Dr. Nikki Lurie. She is the Assistant Secretary for Preparedness and Response with the Department of Health and Human Services. In this capacity, she serves as the Secretary's principal advisor on matters related to bioterrorism and other public health emergencies.

Her office is the lead agency for Federal public health and medical preparedness and response, helping the Nation prepare for, respond to, and recover from disasters. She has also served with HHS as the Principal Deputy Assistant Secretary of Health.

Prior to her work at the Department, Dr. Lurie was a senior natural scientist and a professor of health policy at the Rand Corporation and served in Minnesota State government. Dr. Lurie attended college and medical school at the University of Pennsylvania and completed her residency and master's at UCLA. She continues to practice medicine in Washington, DC.

We welcome you, Dr. Lurie.

Let me introduce all of you, and then I'll come back to Dr. Lurie and let her start.

Dr. Robin Robinson is the first and current Director of the Biomedical Advanced Research and Development Authority and the Deputy Assistant Secretary in the Office of the Assistant Secretary

for Preparedness and Response at HHS. Dr. Robinson has vaccine and private sector experience and joined HHS in 2004 to establish the medical countermeasures policy for the national strategy for pandemic influenza.

Dr. Robinson received his bachelor's degree from Millsaps College and a doctoral degree from the University of Mississippi Medical School in medical microbiology. He completed an NIH post-doctoral fellowship with the State University of New York at Stony Brook in molecular oncology.

Robin, welcome.

Dr. Stephen Redd, Rear Admiral Stephen Redd, is with us today—welcome—from the Centers for Disease Control and Prevention, where he serves as the Director of the Office of Public Health Preparedness and Response. Before this role, Dr. Redd was the Director of Influenza Coordination Unit and served as the Incident Commander during the H1N1 pandemic.

He has served as a commissioned officer for 29 years. Dr. Redd is a graduate of Princeton and Emory Universities, and he received his medical degree and trained in medicine at Johns Hopkins. He has received numerous awards, including the Public Health Distinguished Service Medal and Meritorious Service Medal.

Again, welcome, Rear Admiral.

Dr. Luciana Borio—am I close?

Dr. BORIO. Lu Borio.

Senator BURR. Lu Borio joined the FDA in 2008 and is the Assistant Commissioner for Counterterrorism Policy and Director of Food and Drug Administration's Office of Counterterrorism and Emerging Threats. She heads the FDA medical countermeasures initiative and is the acting Deputy Chief Scientist.

Dr. Borio—correct? I thought you stuck another part in there, but—also serves at HHS as the advisor on biodefense programs. In addition to her various roles at FDA and HHS, Dr. Borio was also a senior associate at the UPMC Center for Biosecurity and assistant professor of medicine at the University of Pittsburgh.

She received her M.D. from George Washington University and completed her residency at New York Presbyterian Hospital Cornell Medical Center. She continues to practice medicine at Johns Hopkins Hospital.

Doctor, welcome.

With that, I'll turn to you, Dr. Lurie, for any opening statement you might want to make.

**STATEMENT OF NICOLE LURIE, M.D., MSPH, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC**

Dr. LURIE. Thank you and good morning, Senator Burr and Ranking Member Murray and acting Ranking Member Casey and other distinguished members of the committee.

I'm Dr. Nicole Lurie, the Assistant Secretary for Preparedness and Response, or ASPR, at HHS. As you know, I'm joined by my colleagues today from BARDA, CDC, and FDA. I appreciate the opportunity to talk to you today about our Nation's preparedness and ASPR's successful implementation of the Pandemic and All Hazards Preparedness Acts.

These critical pieces of legislation arose from lessons learned following several disasters and created ASPR, providing the Federal Government with better mechanisms to coordinate preparedness and response activities and support State and local authorities throughout the disaster cycle. ASPR has successfully executed its responsibilities, leveraging the authorities that you have provided.

We've improved the Federal personnel and logistical capabilities deployed in responses, expanded training for our responders, and changed the way we conduct drills and exercises to ensure we're coordinated when disaster strikes. We've also spearheaded new coordination among Federal preparedness grant programs, formally incorporated mental health into response, built regional preparedness coalitions, and developed new guidance to give States flexibility in deploying their human resources in emergencies.

We've dramatically enhanced our focus on children and other potentially at-risk populations, including through a novel collaboration with CMS to better identify and prepare for the needs of electricity dependent and dialysis patients.

To advance the development and procurement of new medical countermeasures, ASPR created an interagency body called the Public Health Emergency Medical Countermeasures Enterprise—it's a mouthful, so I say PHEMCE—developed a multiyear medical countermeasure budget, and used critical authorities to encourage strong partnerships with industry. As you will hear from Drs. Robinson and Borio, these flexibilities have made a tremendous difference.

The National Health Security Strategy provides strategic direction to ensure that efforts to improve the Nation's health security are guided by a common vision, based on sound evidence, and carried out in an efficient and collaborative manner. In ASPR, we believe that strong day-to-day systems are the backbone of strong preparedness and response.

We have reoriented the Hospital Preparedness Program so our programs better link public health and healthcare and encourage healthcare entities in every community to work together through healthcare coalitions. Healthcare coalitions now include nearly three-quarters of the hospitals in the United States as well as EMS providers, emergency management organizations, long-term care facilities, behavioral health, public health agencies, et cetera.

We've witnessed the benefits of these coalitions time and time again, with community responses in Joplin after the tornado, in North Carolina after Hurricane Irene, in West, TX after a chemical plant fire, and along the East Coast after Hurricane Sandy, to name a few. We need to look back no further than Ebola to see how critical it is that public health and medical care work closely together while at the same time recognizing the unique capabilities that each system contributes.

We recognize, however, that communities can be quickly overwhelmed, and when that happens, they need to count on their Federal partners to come through. To that end, we revamped the National Disaster Medical System, and our teams are now on the ground within hours, not days, of requests for help. Over the past 9 years, our operation centers coordinated 120 Federal public health and medical responses.

PAHPA also authorized programs to develop and make available new countermeasures. I will say that 2010 marked an important turning point. Our review of the entire Medical Countermeasures Enterprise resulted in improvements across the entire PHEMCE in the way partners work together and get things done.

The PHEMCE strategy and implementation plan lays out priorities, and the first ever PHEMCE multiyear budget was recently provided to Congress. Together, PHEMCE agencies have over 160 product candidates in the pipeline, and we've added a dozen products to the strategic national stockpile. Eight products have been approved by FDA since 2012. As you'll hear, new capabilities we have up and running have been central to getting Ebola countermeasures into West Africa for clinical trials now underway.

In the years since the passage of PAHPA, we've learned many things about how to become more prepared, how to respond more effectively, how to help communities recover faster and better. However, the most important lesson is that there is no end point to preparedness, no point at which we can dust off our hands, stand back, let down our guard, and say we're done. Our nation's health security requires continuous improvement and constant vigilance. PAHPA and PAHPRA have been critical to these advances in our preparedness.

Before I close, I just want to say a special thank you to you, Mr. Burr, the poppa and grandpoppa of all of these efforts. Thank you, and I'm happy to answer any questions that you might have.

[The prepared statement of Dr. Lurie follows:]

#### PREPARED STATEMENT OF NICOLE LURIE, M.D., MSPH

Good morning Senator Burr, Ranking Member Casey, and other distinguished members of the committee. I am Dr. Nicole Lurie and I serve as the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services (HHS).

I appreciate the opportunity to talk to you today about the Office of the Assistant Secretary for Preparedness and Response (ASPR) and its accomplishments in moving the country forward in preparing for, responding to, and recovering from the adverse health effects of emergencies and disasters. Recognizing lessons learned from disasters including the terrorist attacks on 9/11, the anthrax attacks in 2001, and Hurricane Katrina, ASPR and its predecessor agency were established to improve coordination and direction across the spectrum of HHS preparedness and response activities. Under the Public Health Service Act, as amended by the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA) and the Pandemic and All-Hazards Reauthorization Act of 2013 (PAHPRA), ASPR was established as the lead for HHS emergency preparedness and response and serves as the principal advisor to the Secretary regarding Federal public health and medical preparedness and response to public health emergencies.

#### INTRODUCTION

Over the past 6 years, ASPR has significantly advanced the Nation's preparedness, contributing to enhanced response and more resilient communities that are better prepared to recover from an emergency or natural disaster. We have found innovative ways to identify and protect vulnerable populations, including targeted approaches for children, pregnant women, and people with special medical needs, like those who need dialysis or electrically dependent durable medical equipment. We restructured the National Disaster Medical System teams so they are more flexible, are pediatrics capable, and can provide other specialized capabilities to assist communities after disasters. We developed and now use innovative approaches to stimulate private sector interest in partnering with us to develop medical countermeasures to protect against threats to health. ASPR and the Centers for Disease Control and Prevention (CDC) aligned preparedness grants to State and Local partners to reduce their administrative burden and maximize the return on investment

and are building new tools to assist hospitals and other healthcare coalition members in meeting the medical and public health needs of their communities. Today, we integrate behavioral health into our response to every disaster, recognizing that community-level recovery depends on individual ability to cope with the impacts of disasters. We are galvanizing the scientific community to be ready to conduct research quickly to answer the tough questions your constituents will have for you about their health after disasters.

These advances—vital to our Nation’s health security—have been supported and made possible by the authorities provided in PAHPA and PAHPRA and an incredible team of men and women who comprise ASPR. Under these authorities, ASPR’s responsibilities are broad, and include: overseeing advanced research, development, and procurement of resulting medical countermeasures, coordinating with health care systems, and providing integrated policy and strategic direction under the National Response Framework. In addition, ASPR directs medical and, with CDC, public health grants and cooperative agreements, provides leadership in international programs and policies with global impact, and has developed and submitted a 5-year budget plan for countermeasure priorities. ASPR oversees the National Disaster Medical System (NDMS), the Hospital Preparedness Cooperative Agreement Program (HPP), and the Biomedical Advanced Research and Development Authority (BARDA). Through guidance documents like the National Health Security Strategy (NHSS) and Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (SIP), ASPR leads the path forward for our partners and stakeholders.

Since PAHPRA was passed in 2013, ASPR has provided to the Congress critical requested deliverables including a new National Health Security Strategy for 2015 to 2018, and a National Health Security Review for 2010 to 2014. In addition, ASPR provided a 5-year Medical Countermeasure budget plan, a new PHEMCE SIP, an Interagency Coordination Plan with the Department of Defense regarding medical countermeasures, established a new National Advisory Committee on Children and Disasters, and issued guidelines for temporary reassignment of State and tribal public health personnel, State pandemic influenza plans, a public health and medical situational awareness strategy, and an annual review of the Strategic National Stockpile (SNS).

#### IMPROVING THE MEDICAL COUNTERMEASURE ENTERPRISE

Recently, my office released the 2014 PHEMCE SIP, which guides medical countermeasure priorities for short, middle, and long-term projections. The PHEMCE is one of many great examples of ASPR’s whole-of-government approach. In 2006, ASPR established the PHEMCE to be the single Federal coordinating body that oversees the entire medical countermeasure lifecycle across the various Federal departments and agencies. My office manages the PHEMCE in partnership with other HHS agencies including the National Institutes of Health (NIH), the Food and Drug Administration (FDA), CDC, and BARDA, along with interagency partners such as the Department of Defense (DoD), the Department of Homeland Security (DHS), the Department of Agriculture (USDA), and the Department of Veterans Affairs (VA). Prior to the PHEMCE, Federal efforts were fragmented, and collaboration with our industry partners was limited. With a variety of potential threats requiring substantial investment, we needed a method to make sure we were not wasting resources on duplicative ventures. The resulting governance process and decision framework provides means to coordinate across government, prioritize investments, and get results.

As you know, HHS recently provided estimated funding requirements for HHS PHEMCE agencies, including NIH, ASPR/BARDA, FDA, and CDC, in the first-ever PHEMCE multi-year budget. The multi-year budget describes a plan for funding BARDA’s Advanced Research and Development programs and Project BioShield over 5 years; to maintain the current level of preparedness at the SNS; to continue the NIH investments in biodefense basic research and development; and to sustain FDA’s Medical Countermeasure Initiative, initially recommended by the 2010 PHEMCE Enterprise Review. It is a critical companion to the PHEMCE SIP in accurately projecting the resource estimates required for end-to-end medical countermeasure life-cycle management as a product, or candidate product, moves through development, licensure, acquisition, and stockpiling.

#### THE BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

Coordination made possible through the PHEMCE continues to drive progress and success in making medical countermeasures available. BARDA has made great progress, from a time when there were almost no medical countermeasures in the

pipeline, to a robust pipeline with over 160 candidate medical countermeasures for chemical, biological, radiological, and nuclear (CBRN) threats and pandemic influenza. Eight of these products have received FDA approval in the last 3 years including countermeasures for anthrax, botulinum and pandemic influenza. Moreover, BARDA procured 12 novel medical countermeasures for the SNS through Project BioShield, including those for smallpox, anthrax, botulinum, radiologic/nuclear emergencies and chemical events. Since 2007, BARDA has supported the development of 18 influenza medical countermeasures, including those used during the 2009 H1N1 pandemic and others stockpiled for potential avian influenza H5N1 and H7N9 outbreaks.

We are on a trajectory to make available 12 new medical countermeasures through Project BioShield procurements in the next 5 years. These medical countermeasures include next generation anthrax vaccines, new smallpox vaccines, biodosimetry diagnostic devices, thermal burn radiation drug and skin replacement therapies, radiation cell therapies, new antibiotics to counter the ever growing public health threat from antimicrobial resistance, and new chemical antidotes.

We have moved from a one-bug, one-drug approach in countermeasure development, to a capabilities-based approach in which we are able to make novel medical countermeasures when they are most needed during an emergency. With the establishment of the three Centers for Innovation in Advanced Development and Manufacturing in 2012 and a Fill Finish Manufacturing Network comprised of four aseptic filling manufacturers in 2013, we are developing, manufacturing, and filling medical countermeasures for CBRN threats like anthrax, for emergency situations like pandemic influenza like the H7N9 vaccines in 2013, and for emerging infectious diseases. In keeping with the parameters of our public-private partnership, these state-of-the-art facilities may also be used by our private sector partners to develop new vaccines and drugs for the open market.

We've also made huge progress in pandemic influenza preparedness. In 2004, the Nation had a single domestic influenza vaccine manufacturer. Due to planning, foresight and support across the Federal Government, and robust public-private partnerships, we now have robust and rapid domestic manufacturing capacity for pandemic influenza vaccines, capable of rapidly producing vaccines and other biologics against pandemic influenza and other emerging threats.

#### EMERGENCY PREPAREDNESS AND RESPONSE

HHS is the coordinator and primary agency for the Public Health and Medical Services Emergency Support Function of the National Response Framework. Our day-to-day work involves supporting local and State partners to build stronger, more resilient communities. Ultimately, communities should be able to respond to a wide-range of threats to public and medical health emergencies on their own, limiting the need for Federal assets to augment response. Critical to this effort is the National Hospital Preparedness Program—or HPP, which strengthens the day-to-day activities necessary to maintain readiness by providing resources to State, territorial, and local awardees.

Over the last few years, ASPR has shifted the focus of HPP from preparing one hospital at a time to preparing all of the healthcare entities in a community through Health Care Coalitions. Health Care Coalitions are formal, collaborative networks of hospitals, health care organizations, public health providers, emergency management, emergency medical services, and other public and private sector health care partners within a defined region. We saw the importance of this first-hand, during Hurricane Sandy, when nursing homes and hospitals needed to evacuate, and mobile satellite emergency units funded in part by HPP were used to relieve pressure on the remaining facilities. Further, hospitals can now communicate with other responders through interoperable communications systems; track bed and resource availability using electronic systems; protect health care workers with proper equipment; train health care workers on how to handle medical crises and surges; develop fatality management, hospital evacuation, and alternate care plans; and coordinate regional training exercises. There are many more examples of how HPP has demonstrated a return on investment, notably during the outbreak of fungal meningitis in Michigan; the ammonium nitrate explosion at a fertilizer facility in West, TX; and during the bombings at the Boston Marathon.

#### ASPR HAS FOCUSED ON THE NEEDS OF AT-RISK POPULATIONS

The underlying goal of my office is to make sure our Nation is secure and resilient when confronting diverse incidents with challenging health consequences. The National Health Security Strategy guides the Nation in achieving that goal. The first NHSS was submitted to the Congress in 2009. The second quadrennial report builds

on the lessons of the first 4 years, and was submitted to the Congress, on time, in December 2014.

Central to the NHSS is the understanding that resilient communities include healthy individuals and families with access to health care, both physical and psychological, during routine and emergency situations. Enhanced resilience is critical to mitigating vulnerabilities, reducing negative health consequences, and rapidly restoring community functioning. ASPR provides subject matter expertise, education, and coordination to make sure the functional and access needs of at-risk individuals and behavioral health issues are integrated with national public health and medical emergency preparedness, response, and recovery activities, as required by PAHPA and PAHPRA.

ASPR works to promote strategies for building individual and community resilience that are inclusive of both behavioral health and the functional needs of at-risk individuals. Such strategies will improve communities' ability to maximize resources, meet needs, and recover from the adverse health consequences of public health emergencies and disasters at the individual and community levels. PAHPRA provided my office with the tools necessary to strengthen our capabilities and highlighted the need to address the risks and challenges faced by children during emergencies and disasters. Just this past year, we established the National Advisory Committee on Children and Disasters to further address the public health needs of children affected by disasters, a critically important component of our response efforts.

#### CONCLUSION

In the past 6 years, we have learned many things about how to become more prepared, how to respond more effectively, and how to recover faster. However, it is critical that we recognize that there is no end point in preparedness—and that maintaining a strong, steady State of preparedness is our new normal. Our objective has been to create a system of flexible and nimble capabilities which can be used in response to the range of threats we face. PAHPA and PAHPRA have given us many of the tools we need, from programs like HPP and BARDA to authorities like emergency use authority (EUA) flexibility. We have used each and every one of them, including in the Ebola crisis. We appreciate the support and partnership we have had with this committee and with the Congress and look forward to continuing to work together to enhance our Nation's health security.

Senator BURR. Thank you, Dr. Lurie.  
Dr. Robinson.

#### **STATEMENT OF ROBIN A. ROBINSON, Ph.D., DIRECTOR, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY, DEPUTY ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, WASHINGTON, DC**

Ms. ROBINSON. Good morning, Chairman Alexander, Ranking Member Casey, Senator Burr, and other distinguished members of the committee. First, thank you for your continued support in our mission to make the Nation better prepared and for the opportunity to update you today on medical countermeasures for public health preparedness and response.

I'm Dr. Robin Robinson, Director of the Biomedical Advanced Research and Development Authority, or BARDA, the Deputy Assistant Secretary for the ASPR, Dr. Lurie, as well as a former vaccine developer in industry. BARDA is the full-time Federal Government agency created in 2006 by the Pandemic and All Hazards Preparedness Act to support advanced research and development and procurement of novel and innovative medical countermeasures that address the needs of the entire Nation for man-made threats and emerging infectious diseases, like the 2009 H1N1 pandemic and the current Ebola epidemic.

Medical countermeasure development is risky, lengthy, and expensive, with many inexperienced developers failing, and, in the past, many larger pharmaceutical companies avoiding the sector

completely. BARDA serves as a bridge over a critical gap referred to as the Valley of Death in medical countermeasure development by transitioning product candidates from early development at NIH to advanced development toward FDA approval and potential procurement through direct funding, public-private partnerships, and technical core service assistance programs.

Seven years ago, I agreed to take up the mantle as BARDA's first director because I believed that the country needed medical countermeasures for protection against bioterrorism and pandemic diseases. I also believed that PAHPA's creation of BARDA was the appropriate course adjustment for the long journey to win this fight. Last, I believed that BARDA's talented and dedicated scientist staff and I could succeed in this mission.

Today, I am pleased to report to you that BARDA is living up to PAHPA's vision of making our country better prepared and secure against these threats with the right medical countermeasures. I'll briefly walk you through what we have done pre- and post-PAHPA and what we plan to do going forward.

PAHPA directed BARDA to promote countermeasure advanced research and development. Before PAHPA, our medical countermeasure product development pipeline was very small, primarily for anthrax, smallpox, and pandemic influenza. Now there are more than 160 medical countermeasures for all known CBRN threats and pandemic influenza, including those for special populations.

Nearly 20 of these medical countermeasures have been approved by the FDA since 2007 with many more products expected to receive approval in the next several years. Before PAHPA, only three BioShield products were in the strategic national stockpile. Now there are 12 products for biothreats, chemical threat agents, radiation illnesses, and 12 more new products expected within the next several years.

Under the national strategy for pandemic influenza and using PAHPA authority, BARDA expanded domestic pandemic influenza vaccine manufacturing capacity multifold, stockpiled H5N1 and H7N9 vaccines, and provided influenza medical countermeasures for the 2009 H1N1 pandemic. Today, BARDA is supporting development and manufacturing of promising Ebola vaccine and therapeutic candidates.

For the future, we are launching major new initiatives to address antimicrobial drug resistance and biothreats primarily, with secondary benefits for high-priority public health pathogens and to enhance pandemic preparedness with new universal influenza vaccines and immunotherapeutics that will also benefit seasonal influenza.

PAHPA directed BARDA to promote innovation to reduce the time and cost of countermeasure advanced research and development. Prior to PAHPA, there were no innovation investments under Project BioShield. Since PAHPA, we have stimulated innovations like synthetic biology in the development and manufacturing of vaccine and therapeutic candidates and helped modernize the vaccine industry.

Going forward, we will work with our partners on a transformative and cost-saving innovation called continuous manufac-



turing that may change how and where and how much we spend for medical countermeasures.

PAHPA directed BARDA to facilitate collaboration with respect to medical countermeasure advanced research and development. Under PAHPA, BARDA has collaborated closely with our Federal partners in both medical countermeasure preparedness and response. Further, BARDA has made public-private partnerships with industry a standard business practice by partnering with more than 90 companies, large and small, and more than 25 academic institutions.

Cost-sharing public-private partnership examples include the utilization of the other transactional authority authorized under PAHPA to create a novel model for the development of new antibiotics and the establishment of three Centers for Innovation in Advanced Development and Manufacturing. The centers are part of our overall core service assistance programs that help medical countermeasures daily and provide a national medical countermeasure response.

In conclusion, State- and terrorist-sponsored actors using CBRN agents of mass destruction and recurring infectious diseases like pandemic influenza and Ebola are real threats to our national health security. BARDA's progress in medical countermeasure preparedness and response to these threats through our product development acumen, public-private partnerships, and commitment to innovation may also serve as a model to help make Americans healthier.

However, the job is not yet done. Continued and more vigorous investment into BARDA's mission will ensure that our partners and we are able to better prepare the Nation for the next known and unknown threat.

Thank you.

[The prepared statement of Ms. Robinson follows:]

PREPARED STATEMENT OF ROBIN A. ROBINSON, PH.D.

Good morning, Senator Burr, Ranking Member Casey, and distinguished members of the committee. Thank you for the opportunity to speak with you today about our Government's public health preparedness and response medical countermeasure efforts and challenges. I am Dr. Robin Robinson, Director of the Biomedical Advanced Research and Development Authority (BARDA) and Deputy Assistant Secretary for Preparedness and Response (ASPR). I am happy to testify today with the ASPR, Dr. Nicole Lurie, and my other HHS colleagues.

BARDA is the Federal Government agency, within the Office of the Assistant Secretary for Preparedness and Response (ASPR), created in 2006 by the Pandemic and All-Hazards Preparedness Act (PAHPA) and reauthorized by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) to support advanced research and development and procurement of novel and innovative medical countermeasures. These medical countermeasures—vaccines, therapeutics, antiviral and antimicrobial drugs, diagnostics, and medical devices—address the needs of the entire nation to mitigate the medical consequences of man-made chemical, biological, radiological, and nuclear (CBRN) agents of terrorism and naturally occurring and emerging threats like the 2009 H1N1 pandemic, the 2013 H7N9 influenza outbreak, and the current Ebola epidemic.

Medical countermeasure development is risky, lengthy, and costly with many inexperienced developers failing and many larger pharmaceutical companies avoiding the sector completely. BARDA serves as a bridge over a critical gap in medical countermeasure development. BARDA transitions product candidates from early development into advanced development toward potential Food and Drug Administration (FDA) approval and stockpile procurement through direct support, public-private partnerships, and technical core service assistance programs.

The Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) establishes product specific requirements for CBRN medical countermeasures based on threat scenarios and Material Threat Assessments performed by the Department of Homeland Security (DHS). The National Institutes of Health (NIH) launch discovery and early stage development of product candidates from academic and industry partners for transition to BARDA. In turn, BARDA supports and assists these product candidates through advanced research and development toward FDA approval, until they are sufficiently mature to be acquired and potentially stockpiled under Project BioShield at the Centers for Disease Control and Prevention's (CDC) Strategic National Stockpile (SNS) or at commercial vendors. Upon FDA approval, the financial responsibility of purchasing medical countermeasures transfers from BARDA under Project BioShield to the CDC/SNS for the stockpile and delivery phases. Finally, in public health emergencies, like we saw in the H1N1 influenza pandemic and today during the Ebola epidemic, BARDA, under the emergency management authorities of ASPR, assumes a response posture, interfacing with other Federal agencies and manufacturers to develop, produce, and test products for FDA review and approval and distribution by CDC to State and local providers.

BARDA is the only Federal Agency that operates in the advanced development space of product development. Advanced development includes critical steps needed to transform a candidate to a product that is ready to use. These steps include: optimizing and validating manufacturing processes such that products can be made at commercial scale; optimizing product formulations, storage, and product longevity and effectiveness; creating, optimizing, and validating assays to assure product integrity; conducting late-stage clinical safety and efficacy studies; and carrying out pivotal animal efficacy studies that are often required for approval of CBRN medical countermeasures.

PAHPA directed BARDA to promote countermeasure and product advanced research and development. Since its creation, BARDA has built a comprehensive and formidable advanced development product pipeline comprised of more than 160 medical countermeasures for CBRN threats and pandemic influenza. Eight of these products from influenza vaccines to anthrax antitoxins have received FDA approval in the last 3 years alone; a total of nearly 20 have been approved since 2007. The anthrax and botulinum antitoxin products were the first Project BioShield products approved by FDA under the Animal Rule. Twelve of these products, ranging from anthrax and smallpox vaccines to anti-neutropenia cytokine therapeutics for radiation illness have been procured under Project BioShield with another 12 ready for Project BioShield procurement between now and the end of fiscal year (FY) 2018. Many of these Project BioShield medical countermeasures were made possible through use of Advanced and Milestone Payment Authorities designed by PAHPA to provide small companies with greater financial stability. Further BARDA has supported the development and manufacturing of 18 influenza vaccines, antiviral drugs, and diagnostics that were used in the 2009 H1N1 pandemic and stockpiled for avian influenza H5N1 and H7N9 outbreaks; a set of industry and academic partnerships enhanced through our PAHPA authorities (*e.g.*, antitrust exemption). To better serve the needs of special populations, BARDA has led the development of many medical countermeasure candidate formulations for children, like Prussian Blue, a treatment for internal radiation contamination, and solithromycin, a new antibiotic, as well as a smallpox Modified Vaccinia Ankara vaccine for immunocompromised individuals, which was transitioned from the National Institute of Allergy and Infectious Diseases. BARDA is currently supporting development and manufacturing of several Ebola vaccine and therapeutic candidates destined for clinical trials in West Africa. BARDA's work on Ebola medical countermeasures has marked a milestone, as the medical countermeasure development pipeline now includes at least one product candidate for each of the DHS's Material Threat Determinations and pandemic influenza.

PAHPA directed BARDA to promote innovation to reduce the time and cost of countermeasure and product advanced research and development. BARDA has stimulated innovation in the development and manufacturing of vaccine and therapeutic candidates across the pharmaceutical industry. Innovation investments have transitioned a platform technology using a novel bacterial expression system into a next generation anthrax vaccine candidate by coupling that expression system with rational genetic design technology; the objective of which is an anthrax vaccine with increased stability and production yields, and thus a lower overall product cost. BARDA partnered with industry to use synthetic biology technology to generate influenza vaccine seed strains. In 2013, this technology was pivotal in making pre-pandemic H7N9 bulk vaccine for stockpiling in record time by cutting several weeks off the usual timeframe to make influenza vaccines. BARDA began working with industry partners last fall to develop new Ebola monoclonal antibodies rapidly using

the latest innovations in monoclonal antibody development; now we are testing these new Ebola antibody candidates in non-human primate challenge studies; if these studies are successful, these products will move into clinical trials later this year. BARDA has kept a keen eye on and supported innovative technologies that may enhance existing medical countermeasures or generate new transformative medical countermeasures at lower costs and with longer shelf lives.

PAHPA directed BARDA to facilitate collaboration between the Department of Health and Human Services and other Federal agencies, relevant industries, academia, and others, with respect to such advanced research and development. BARDA has established its medical countermeasure development pipeline by collaborating with Federal partners, primarily NIH, CDC, FDA, and the Department of Defense, and by making many public-private partnerships with industry and academia. BARDA partnerships have included nearly 90 pharmaceutical and biotechnology companies, both large and small, and more than 25 academic and other institutions since 2006. BARDA, with vaccine manufacturers, has established the first and largest pre-pandemic influenza vaccine stockpile in the world, one that could, if necessary, vaccinate tens of millions of Americans against potential H5N1 and H7N9 pandemics. BARDA utilized the Other Transaction Authority authorized under PAHPA to create a novel cost-sharing public-private partnership with industry for the simultaneous development of multiple new classes of antibiotics for biothreats and high-priority public health pathogens. Further, BARDA, industry, and academia have entered into partnerships designated as the Centers for Innovation in Advanced Development and Manufacturing (CIADM) to assist inexperienced medical countermeasure developers, expand modernized domestic pandemic influenza vaccine manufacturing capacity, ensure nimble and flexible manufacturing capabilities for emerging infectious threats in public health emergencies, and provide workforce training to the next generation of vaccine developers and manufacturers. Today the CIADMs are working on anthrax and Ebola medical countermeasures.

Building on the National Strategy for Pandemic Influenza, BARDA has collaborated with industry and Federal partners to: (1) support advanced development of new influenza vaccines, antiviral drugs, and diagnostic devices leading to multiple FDA approvals for the U.S. market; (2) improve influenza vaccine manufacturing resulting in greater vaccine production yields and availability sooner; (3) build and maintain stockpiles of pre-pandemic influenza vaccines for the critical workforce and antiviral drugs at the Federal and State levels; and (4) expand domestic and global pandemic influenza vaccine manufacturing infrastructure and capacity multifold.

To save cost and time in product development and manufacturing, BARDA has established a medical countermeasure infrastructure comprised of core service assistance programs to assist product developers on a daily basis while ensuring rapid and nimble response in a public health emergency. BARDA has employed this medical countermeasure infrastructure for development of CBRN medical countermeasures on a routine basis and is now using them in the current Ebola response by supporting the development and manufacturing of several Ebola therapeutics and vaccines. BARDA's Nonclinical Studies Network (NCSN), which was established in 2010 and is comprised of 17 high-biocontainment laboratories in the United States and the United Kingdom, has developed qualified animal models for CBRN threats, performed animal-challenge studies for CBRN medical countermeasures, and evaluated potential CBRN medical countermeasure candidates in these animal models prior to BARDA investment. Today NCSN is conducting critical animal challenge studies for promising Ebola monoclonal and antiviral drug therapeutic candidates. BARDA's three CIADMs are helping to develop anthrax vaccines and are expanding the production of new and existing Ebola monoclonal antibodies similar to ZMapp in mammalian cells. BARDA's Fill Finish Manufacturing Network, established in 2013 with four contract manufacturing organizations having aseptic filling capabilities in the United States, is now being used to formulate and fill multiple Ebola antibody and vaccine candidates into vials for clinical efficacy studies in West Africa. Two contract research organizations among the five members of our clinical studies network are working with BARDA scientists and with CDC in-country to conduct Ebola vaccine clinical trials in Sierra Leone. BARDA's modeling unit, which routinely provides medical consequence modeling of CBRN threats to inform medical-countermeasure requirements, generated key models and forecasts on the impacts of medical-countermeasure intervention on the epidemiology of the 2009 H1N1 pandemic, the 2013 H7N9 outbreaks, and the current Ebola epidemic in West Africa. The investments that BARDA has made in our national medical-countermeasure infrastructure since 2010 are playing a major role in the Nation's response to the current Ebola epidemic and will become even more vital for medical-countermeasure responses to public health and national security emergencies in the coming years.

Since PAHPA, FDA and BARDA have greater scientific and regulatory engagement, both in regard to the requirements for Emergency Usage Authorization and Animal Rule, as well as all aspects of regulatory approval throughout the medical countermeasure development pipeline. Currently BARDA and FDA are working together to implement a framework for selection of medical countermeasure candidates needing Regulatory Development Plans as required in PAHPRA.

BARDA has developed multiple opportunities for government, industry, and academic stakeholders to engage us with regard to medical countermeasure research, development, innovation, and stockpiling. The PHEMCE's website,<sup>1</sup> managed by BARDA, serves as a portal for updated information on medical countermeasure goals, priorities, programs, funding opportunities, meetings, and procurement policies and processes. Through this portal, stakeholders can arrange meetings with BARDA and other PHEMCE partners via the BARDA-coordinated Tech Watch program that enables companies and others to discuss product candidates in detail and to understand PHEMCE goals, priorities, and procurement processes. Through the TechWatch program, BARDA has met with an average of more than 150 stakeholders each year on CBRN and pandemic influenza medical countermeasures; in the last year, we've met with an additional 130+ stakeholders on Ebola medical countermeasures. Data have shown that those companies that visit BARDA through the Tech Watch program have a much greater chance of success than those not meeting with BARDA for assistance on technical issues and procurement processes. Additionally, BARDA hosts Industry Day, an annual 3-day event in Washington, DC, where BARDA presents to 700+ stakeholders a status report on the BARDA-funded medical countermeasure portfolio, new programmatic initiatives and funding priorities. Industry Day also offers a concentrated series of TechWatch-like sessions to meet individually with stakeholders. ASPR's contracting office also provides presentations on current procurement policies and processes and provides assistance on contracting issues. BARDA also meets regularly with medical associations, industry alliances, State and local health department associations, and first-line end users across the United States to seek their input on BARDA medical countermeasure programs and initiatives. BARDA's stakeholder outreach demonstrates further our commitment to partnerships with many different sectors and fulfills PAHPA's directive to facilitate collaboration on medical countermeasure development.

PAHPRA extended, reauthorized, or amended many of the authorities that were initially enacted in PAHPA and that BARDA has utilized successfully to establish an advance-development medical-countermeasure pipeline, invigorate Project BioShield with new products, and enable BARDA to meet pandemic influenza medical countermeasure goals. More importantly, PAHPRA reauthorized funding for BARDA Advanced Research and Development programs and the Special Reserve Fund for Project BioShield through fiscal year 2018. The recently released PHEMCE Multi-Year budget details BARDA's plan for utilizing these resources. However, substantial returns on investment seen already in medical countermeasure candidate development and innovative technologies are leading to mature and FDA-approved products and national medical countermeasure infrastructure assets are becoming mature. Major new initiatives in the coming years will include development of products that address our core mission space—man-made and emerging infectious-disease threats—that also will pay dividends in everyday public healthcare. Specifically, BARDA's focus will expand toward development of new classes of antibiotics and new diagnostics to combat antimicrobial drug resistance primarily for biothreats but also public health pathogens, as appropriate; universal influenza vaccines to afford more effective control of seasonal influenza and better preparedness for pandemic influenza; influenza immunotherapeutics to mitigate the emergence of drug resistance to the present classes of influenza antiviral drugs; and continuous manufacturing of pharmaceutical products that may transform where and how we make medical countermeasures in the next 20 years. These new initiatives and the lessons learned from Ebola coupled with BARDA's medical countermeasure advances provide a compelling argument for BARDA to create a new Emerging Infectious Disease program in the coming year.

#### CONCLUSIONS

State- or terrorist-sponsored actors using chemical, biological, nuclear and radiological agents of mass destruction, and recurring natural events including pandemic influenza and emerging infectious diseases like Ebola present real and present health threats to the Nation. BARDA has made significant progress in developing and acquiring medical countermeasures that can address the catastrophic medical

<sup>1</sup> [medicalcountermeasures.gov](http://medicalcountermeasures.gov).

consequences of many of these threats. BARDA's progress has been not just in medical countermeasure preparedness, but in the establishment of a rapid and nimble response national infrastructure to develop, manufacture, and test in animals and humans new medical countermeasures for known and unknown emerging infectious diseases. Authorities and responsibilities created by the Project BioShield Act, PAHPA, and PAHPRA including the establishment of BARDA have demonstrated a successful model to address market failures and high priority USG needs.

Going forward, it is important that we maintain our medical countermeasure preparedness in areas where we have succeeded against key threats, continue medical countermeasure development and manufacturing where we are not yet finished, and reach forward toward transformational medical countermeasure innovations that may bring both more rapid and better preparedness and response capabilities at less expense to these threats. Advancing BARDA's mission will help ensure that we are prepared to face the next Ebola epidemic, influenza pandemic, anthrax attack, or unknown pathogen. BARDA is prepared to meet those challenges and provide resources, expertise, and technical assistance for promising and transforming vaccine, therapeutic and diagnostic candidates.

Senator BURR. Thank you, Dr. Robinson.  
Dr. Redd.

**STATEMENT OF STEPHEN C. REDD, RADM, M.D., DIRECTOR,  
OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RE-  
SPONSE, CENTERS FOR DISEASE CONTROL AND PREVEN-  
TION, ATLANTA, GA**

Dr. REDD. Good morning, Senator Burr, Senator Casey, and Senator Alexander. It's a pleasure to be here today to talk with you about our efforts to improve the state of public health preparedness. I am Rear Admiral Stephen Redd. I'm Director of CDC's Office of Public Health Preparedness and Response.

I'll focus my remarks on two programs this morning. The first is the support to State and local governments, and the second is the strategic national stockpile. I'll also focus on mechanisms or processes that we use to coordinate those activities.

The terrorist attacks of September 11th and the anthrax attacks that followed shortly thereafter brought to light key weaknesses in the U.S. public health infrastructure. In response, the U.S. Government increased efforts to ensure that public health was part of emergency responses and also part of planning and preparing for those responses.

Since 2002, CDC has awarded more than \$9 billion to improve preparedness at the State and local level through a cooperative agreement program known as the Public Health Emergency Preparedness program, and that's commonly known by its acronym of PHEP, but I will limit my use of that acronym. This program supports 62 awardees, all 50 States, 8 territories, and 4 directly funded cities. The funds support staff, they support planning, exercises, training, and the procurement of equipment.

I'm going to now talk about what else these grantees do. They're required to conduct at least one exercise per year and evaluate their performance with an after-action review. They also use real world events to test their operational readiness.

I'll give an example of how this process has led to an intervention through PAHPRA. In the H1N1 influenza pandemic, State governments recognized that they had people working for them that were funded by Health and Human Services but in programs that weren't related to response, and they couldn't move them from those activities to the higher priority.

Through PAHPRA, this problem was corrected, and now when there's a federally declared public health emergency, it's possible to move people from the work that they were doing to respond to public health emergencies with the appropriate oversight.

I'll turn now to the strategic national stockpile. As you know, this is a Federal asset that manages and delivers lifesaving medical countermeasures. It contains pharmaceuticals, critical medical supplies, Federal medical stations, and medical equipment. It's currently valued at \$6.3 billion, and we work closely within the Public Health Emergency Medical Countermeasure Enterprise to prioritize investments in the strategic national stockpile as well as in the upstream of development and production.

We also offer training and technical assistance to State health departments which are the recipients of these materials when they're deployed. We make sure that the knowledge and the skills are available at the State and local level to actually use these products when there is a need.

To conclude, public health threats are everywhere, from the re-emergence of measles, which was eliminated from the United States in the year 2000, to Ebola, a threat from the other side of the world, to an earthquake that can strike suddenly. The public health system must be ready to respond.

Due to investments made by Congress, the Nation is better prepared to prevent and respond to public health emergencies now than before September 11th. As you've heard from the other speakers, preparedness requires ongoing work. We have to learn from our responses and adapt and be ready to adapt as we face new threats.

CDC will continue to work in this system, coordinating with State, tribal, and local health departments and within the Federal family to keep the public safe. I look forward to our continuing to work together in this important area, and I'd be glad to answer any questions.

Thank you.

[The prepared statement of Dr. Redd follows:]

PREPARED STATEMENT OF STEPHEN C. REDD, RADM, M.D.

Good morning Chairman Burr, Senator Casey, and members of the committee. I am Rear Admiral Stephen Redd, Director of CDC's Office of Public Health Preparedness and Response. I am pleased to appear before the committee today to discuss the state of public health preparedness in the United States and the role that the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) and other legislation play in improving the health security of the Nation.

CDC advances the health security of the Nation by helping communities prepare for, respond to, and recover from all hazards, including chemical, biological, radiological, and nuclear threats; natural disasters; and epidemics (Influenza). Whether the hazard is naturally occurring (Ebola, Middle East Respiratory Syndrome, and hurricanes), accidental (the 2014 West Virginia chemical spill) or intentional (Boston Marathon bombings and anthrax attacks), effective public health emergency response depends on building, maintaining and constantly improving the capability of State and local health departments to prepare for and respond to public health emergencies. The all-hazards approach to public health preparedness and response fosters development of emergency-ready public health departments that are flexible and adaptable to the needs of a particular event.

In support of the National Strategy to Combat Antibiotic Resistance Bacteria (CARB) released in September 2014, CDC is also working with other HHS agencies and executive branch departments to address the growing threat of antibiotic resistance. Without rapid and coordinated action, antibiotic resistance threatens public

health progress made over the last century from the discovery and development of antibiotic drugs, thereby threatening patient care, economic growth, public health, agriculture, economic security, and national security. The President's fiscal year 2016 budget supports implementation of the National Strategy by nearly doubling the amount of Federal funding for combating and preventing antibiotic resistance to more than \$1.2 billion. The funding will improve antibiotic stewardship; strengthen antibiotic resistance surveillance and prevention capacity; and drive research innovation in the human health and agricultural sectors.

#### ROLE OF STATE AND LOCAL PUBLIC HEALTH AGENCIES

State and local public health agencies are the lead entities in public health preparedness and response. CDC provides ongoing technical assistance and, if requested, will provide on-the-ground personnel to assist with a state's response effort. For example, CDC personnel are providing laboratory capacity and communications support to California public health agencies in response to the current measles outbreak. Investments in preparedness since 2001 have greatly increased the Nation's public health preparedness for all hazards. One of the lessons learned as a result of responding to the 9/11 and anthrax attacks was that State and local health departments lacked critical capabilities needed to mount an emergency response, and the Nation's public health system also was unable to provide essential public health services during an emergency. Health departments lacked laboratory networks, electronic disease surveillance systems, risk communication networks, and emergency operations centers.

Successful State and local response to public health emergencies depends upon many factors, including a capable State and local public health and healthcare system. Since 2002, CDC has awarded more than \$9 billion to improve preparedness at the State and local level, first through the Cooperative Agreement for Preparedness and Response to Bioterrorism, and then through the Public Health Emergency Preparedness (PHEP) cooperative agreement authorized by the Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA) and reauthorized as PAHPRA in 2013. PHEP currently supports 62 awardees—including all 50 States, 8 territories and freely associated States, and directly funded cities (New York City; Washington, DC; Chicago; and Los Angeles)—according to a base-plus population formula prescribed by statute, which ensures a minimum amount of funding to each awardee. These funds support staff, enable exercises, provide for training, pay for equipment, and provide other services essential to maintaining preparedness. In addition, CDC personnel help PHEP awardees improve their performance by sharing knowledge, useful practices and lessons learned along with the tools and resources needed to identify and address gaps in preparedness capabilities. Congress appropriated \$571 million to CDC to enhance domestic preparedness and response for Ebola including State and local preparedness, laboratory capacity, and expanded entry screening. Cooperative agreements under CDC's PHEP program and the Hospital Preparedness Program (HPP), overseen by the Assistant Secretary for Preparedness and Response (ASPR), are managed through a joint funding opportunity announcement. This collaboration reduces the administrative burden on the awardees through a single application process for both cooperative agreements.

In 2011, CDC published the *Public Health Preparedness Capabilities: National Standards for State and Local Planning* to better focus the preparedness activities of State and local health departments.<sup>1</sup> The 15 capabilities serve as national public health preparedness standards and help ensure Federal preparedness funds are directed to priority areas. State, local and territorial health departments allocate PHEP funds based upon their strategic priorities. Awardees devote nearly 50 percent of their funding to building and sustaining Public Health Surveillance and Epidemiological Investigation and Public Health Laboratory Testing capabilities, core public health activities that help protect their communities. Remaining funds are invested in the other 13 capabilities—Community Preparedness, Community Recovery, Emergency Operations Coordination, Emergency Public Information and Warning, Fatality Management, Information Sharing, Mass Care, Medical Countermeasure Dispensing, Medical Materiel Management and Distribution, Medical Surge, Non-Pharmaceutical Interventions, Responder Safety and Health, and Volunteer Management.

Each year the 62 PHEP awardees report data on their current status for each capability. The data and supporting documentation are validated by CDC's Office of Public Health Preparedness and Response. Aggregate awardee scores show increases in 14 of the 15 capabilities over the past 3 years. The 2014 response to

<sup>1</sup><http://www.cdc.gov/phpr/capabilities/index.htm>.

Ebola cases in the United States illustrates one of the impacts of PHEP funding throughout the past decade. Through that funding, State and local health departments across the country built their capability to perform effective contact tracing to help identify individuals who may have been at a higher risk for infection due to contact with a person with Ebola or due to travel from one of the highly affected countries in West Africa.

#### LESSONS LEARNED FROM REAL-LIFE EVENTS

While training and skill development are important, exercises and real-life events provide opportunities to put those skills to work. PHEP awardees are required to demonstrate their capabilities at least once a year by conducting an exercise and evaluating their performance through an after-action review process. Oftentimes, jurisdictions are able to use real incidents in their communities to test operational readiness to respond to public health emergencies. After-action reviews collect data about successes and areas for improvement identified during unexpected incidents, exercises, and planned events such as festivals or concerts that draw large crowds. Data from these reviews are used to identify strengths for sustainment and gaps for future capability development. Use of this information is key to improving performance for the next incident.

The review process following the 2009 national response to the H1N1 Influenza pandemic provides a good example of how identification of an obstacle encountered during a response can be a catalyst for changes that improve preparedness for future events. At the State and local levels, employees supported through Department of Health and Human Services (HHS) grants that were funded by non-influenza programs were not able to assist in response to the flu outbreak due to restrictions on performing tasks outside of the funding for their normal work. In some areas where there were not enough staff for the H1N1 response, this restriction prevented additional State and local staff from performing surveillance or providing vaccinations. Federal and State partners identified this issue, and the Congress provided new authorization in PAHPRA in 2013 that provides a mechanism for States to request that a worker at the State or local level who is funded under programs authorized by the Public Health Service Act be allowed to assist, based on specified criteria, in a response to a federally declared public health emergency. This provides additional flexibility and scalability to support quick and effective responses to public health emergencies.

#### A STRONG LABORATORY NETWORK

Rapid identification of disease is critical to addressing public health threats before they become a crisis. CDC's Laboratory Response Network (LRN) maintains an integrated network of State and local public health, Federal, and international laboratories that can respond to biological, chemical, and other public health threats. The linking of State and local public health laboratories, veterinary, agriculture, and water- and food-testing laboratories is unprecedented and provides for rapid testing, timely notification and secure messaging of laboratory results. The LRN demonstrates a scalable and flexible asset to address public health threats.

In response to the West Africa Ebola outbreak, CDC collaborated with the Department of Defense (DoD) to equip select LRN laboratories around the United States with the ability to quickly and accurately test specimens for the outbreak strain of Ebola virus. Prior to the current outbreak only two LRN laboratories were capable of performing an Ebola test—DoD's U.S. Army Medical Research Institute of Infectious Diseases and CDC laboratories. By August 1, 2014, CDC provided the FDA emergency use authorized DoD assay to 13 LRN public health laboratories in States chosen based on geography and the number of travelers arriving from West Africa. Currently, 55 laboratories in 43 States have completed proficiency testing with the DoD Ebola assay, and CDC continues to work with LRN laboratories to acquire and maintain capacity to handle Ebola specimens.

#### MEDICAL COUNTERMEASURES FOR PUBLIC HEALTH RESPONSES

CDC's Strategic National Stockpile (SNS) manages and delivers life-saving medical countermeasures during a public health emergency. Valued at approximately \$6.3 billion, it is the largest federally owned repository of pharmaceuticals, critical medical supplies, Federal Medical Stations, and medical equipment available for rapid delivery to support Federal, State, and local response to health security threats. If a biological, chemical, radiological, or nuclear event occurred on U.S. soil tomorrow, the SNS is the only Federal resource readily available to respond once State and local medical countermeasure supplies are depleted.



CDC works with ASPR and with other Federal agencies, through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), to prioritize Federal investments in medical countermeasures based on analysis of risk and support of critical markets. SNS procurements and the advanced development and procurement mechanisms managed through ASPR are critical to maintaining production capacity for products with no commercial market and products for which commercial supplies may be insufficient to meet demands during an emergency.

Just as important as having the right medical countermeasure on the shelf in the SNS is knowing our public health partners at the State and local levels will be able to effectively and efficiently receive those assets from the SNS and get them to the individuals in need of treatment or protection in time. For this reason, CDC offers training programs to ensure that our partners have the knowledge and skills they need to distribute and dispense SNS assets in a timely manner, and CDC supports exercises to test the skills of trained responders and evaluate plans for possible improvements. These trainings and exercises help our partners improve their preparedness and establish confidence in their ability to respond.

Jurisdictions face ongoing challenges when planning to dispense medical countermeasures to large populations. Whether it is the availability of staff or infrastructure to support dispensing of medical countermeasures to large populations, few State or local public health agencies have the resources at their disposal to meet the required dispensing timelines. For this reason, CDC engages with the private sector to establish agreements for support of medical countermeasure dispensing. These partners, who range from nationwide retail, pharmacy and hospitality chains to faith-based and community organizations, all make commitments to support dispensing of countermeasures in the communities they serve. These partnerships, when working with local public health officials, improve efficiency, provide additional means to dispense medical countermeasures to populations within the community and reduce the burden on local public health responders during times of urgent need.

#### CONCLUSION

Public health threats are everywhere. From the reemergence of measles, which hadn't been a problem in the United States for years, to the Ebola virus, a threat from the other side of the world, to an earthquake that can strike without warning, the public health system must remain vigilant to protect U.S. residents.

Preparedness is not a destination. It is a process of skill development, using lessons learned to help us adapt to the current environment and better prepare us to address future threats. CDC will continue to work with our Federal, State, territorial, local and tribal partners to ensure necessary capabilities are maintained to keep the public safe. I look forward to our continued partnership with the Congress and would be glad to answer any questions you may have.

Senator BURR. Thank you, Dr. Redd.  
Dr. Borio.

#### **STATEMENT OF LUCIANA BORIO, M.D., ASSISTANT COMMISSIONER FOR COUNTERTERRORISM POLICY, DIRECTOR OF THE OFFICE OF COUNTERTERRORISM AND EMERGING THREATS, DEPUTY CHIEF SCIENTIST (ACTING), U.S. FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD**

Dr. BORIO. Good morning, Chairman Alexander, Senator Burr and Senator Casey, and thank you for calling this hearing. I'm grateful for the opportunity to appear before you today to discuss FDA's preparedness and response efforts.

I can say with confidence that we are much better prepared today because of this committee's actions and your leadership, Senator Burr. PAHPRA established key legal authorities to strengthen our Nation's readiness for public health emergencies.

In 2010, FDA launched its Medical Countermeasures Initiative to deepen our engagement in medical countermeasure activities. This engagement and new authorities, both codified in PAHPRA, have improved FDA's readiness and has allowed us to mount an extraordinary response to the Ebola epidemic in West Africa.

There are currently no treatments or vaccines that have been shown to be safe and effective for Ebola. The FDA is taking tremendous steps to speed the development, manufacture, and availability of these medical products. We have established continuous lines of communication with commercial developers and U.S. Government agencies.

We are reviewing data as they are received. We have worked with product sponsors, international regulators, and the NIH to launch Ebola vaccine trials in record time. We are leveraging our authorities under PAHPRA. We issued EUAs for eight Ebola diagnostic tests, and as mentioned earlier, just 2 days ago, we authorized the first point of care rapid diagnostic test for Ebola.

We collaborated with the NIH on the design of innovative, adaptive, and scientifically rigorous clinical trial protocol to evaluate investigational drugs for Ebola. This clinical trial, which will first test ZMapp, is now positioned in the United States and in Liberia.

These accomplishments were made possible by the hundreds of frontline FDA scientists and medical officers engaged in this response. I would like to thank them for their tireless efforts and unwavering commitment to service. Congressional investment in our FDA program has also led to improved preparedness in a broader way of threats. For example, under our EUA authority, we authorized the use of diagnostic tests for the H7N9 avian influenza virus and the Middle East Respiratory Syndrome coronavirus. In this time period, FDA approved medical countermeasures for anthrax, botulism, plague, seasonal and pandemic influenza. I may add that virtually all of these also carry a pediatric indication, thanks in part to regulatory science.

Just yesterday, we approved an antibiotic drug combination to treat some very serious infections that may involve bacteria resistant to other drugs. Developing countermeasures is highly complex, as you know, and the Ebola epidemic has demonstrated how critical it is to respond with speed and flexibility, but also how important it is to get it right.

When investigation of products are still in the early stages of development, it is possible that some that at first seemed promising may ultimately have little or no effect. The fastest and most definitive way to determine whether a product is safe and effective is through properly designed scientific investigations and clinical trials. In emergencies like this, the urgency to do something may be used as an excuse to conduct studies that are not scientifically sound and may fail to detect harm.

It must be remembered that investigational drugs can have side effects that may harm patients. This is particularly important for Ebola, where many patients survive with basic medical care, and administering a drug that lacks activity and that has significant side effects to vulnerable patients could have disastrous and even fatal consequences.

It's very important that decisions about using investigational products need to be carefully considered. It's essential for safeguarding patient safety and also maintaining the trust of affected populations.

I want to conclude by emphasizing that close cooperation and coordination are essential, and the strong engagement that is evident

among the agencies here today is an example of public health synergy at its best. There is still a tremendous amount of work for us to do, and we are fully committed to leveraging our deep expertise and all of our authorities to the fullest extent to support our Nation's readiness for these serious public health threats.

Thank you for making this happen.

[The prepared statement of Dr. Borio follows:]

#### PREPARED STATEMENT OF LUCIANA BORIO, M.D.

Good morning Mr. Chairman, Ranking Member, and members of the committee. I am Dr. Luciana Borio, Assistant Commissioner for Counterterrorism Policy, Director of the Office of Counterterrorism and Emerging Threats, and Acting Deputy Chief Scientist at the Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to appear today to discuss FDA's efforts to prepare our Nation to mitigate chemical, biological, radiological, and nuclear (CBRN) threats as well as threats from naturally emerging infectious diseases like pandemic influenza and antimicrobial-resistant pathogens.

#### FDA'S MEDICAL COUNTERMEASURES MISSION

FDA plays a critical role in facilitating the development and availability of medical countermeasures to protect the United States from CBRN and emerging infectious disease threats. FDA works closely with its interagency partners through the Public Health Emergency Medical Countermeasures Enterprise (the Enterprise) to build and sustain the medical countermeasure programs necessary to respond effectively to public health emergencies. We also work with the U.S. Department of Defense (DoD) to facilitate the development and availability of medical countermeasures to support the unique needs of the military. The mission of my office is to facilitate the development and availability of these lifesaving products.

In 2010, FDA launched its Medical Countermeasures Initiative (MCMi) to focus increased resources on facilitating the development and availability of medical countermeasures. FDA's scope of operations within its medical countermeasures mission covers a broad range of activities vital to facilitating the development of and access to safe and effective medical countermeasures, including:

- Reviewing medical countermeasure marketing applications and approving those that meet applicable standards for safety and efficacy;
- Providing regulatory advice, guidance and—when appropriate and needed—technical assistance to medical countermeasures product sponsors, U.S. Government partners, international regulators, and international organizations such as the World Health Organization (WHO);
- Supporting efforts to establish and sustain an adequate supply of medical countermeasures, including averting supply disruptions when feasible and, in certain situations, allowing products to be used beyond their expiration dates when supported by our scientific analyses;
- Supporting the development of advanced manufacturing technologies by collaborating with the Department of Health and Human Services (HHS) Biomedical Advanced Research and Development Authority (BARDA) on their Centers for Innovation in Advanced Development and Manufacturing;
- Facilitating access to medical countermeasures that are not yet approved, licensed, or cleared for use, if circumstances warrant, through an appropriate mechanism such as an Emergency Use Authorization (EUA);
- Ensuring that FDA regulations and policies adequately support medical countermeasures development and enable preparedness and response activities;
- Fostering the professional development of our scientists to ensure that FDA personnel maintain the skills and abilities to support the medical countermeasures mission;
- Proactively identifying and resolving regulatory challenges associated with medical countermeasures; and
- Supporting regulatory science to develop the tools, standards, and approaches necessary to assess the safety and efficacy, including quality and performance, of medical countermeasures.

## MEASURES OF SUCCESS

The additional resources that Congress provided to FDA for the MCMi have enabled FDA to hire expert staff and become more deeply and thoroughly engaged in medical countermeasure activities.

This increased engagement, along with new authorities gained under the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) of 2013, which, for example, provided FDA greater flexibility in the issuance of EUAs, has enabled FDA to better respond to emerging public health threats. For example, FDA worked proactively with U.S. Government partners, international partners, and product developers to help facilitate the development and availability of medical countermeasures to respond to the avian influenza A (H7N9) virus and the Middle East Respiratory Syndrome coronavirus (MERS-CoV). FDA authorized the use of three diagnostic tests for the H7N9 virus and one diagnostic test for MERS-CoV, under its EUA authority.

FDA has also taken extraordinary steps to be proactive, flexible, and highly responsive to the Ebola epidemic in West Africa, which has presented a complex range of issues. FDA's efforts include:

- Working to help expedite the development and availability of medical products to detect, prevent, and treat Ebola virus disease, by providing scientific and regulatory advice to commercial developers and U.S. Government agencies that support medical product development;
- Working with product sponsors, international regulators, WHO, and the National Institutes of Health (NIH) to launch Ebola vaccine trials in record time;
- Collaborating with NIH to help with the design of an innovative and robust common clinical trial protocol to evaluate investigational treatments for Ebola;
- Collaborating extensively with WHO and our international regulatory counterparts to exchange information about investigational products for Ebola in support of international response efforts and to achieve regulatory harmonization, where possible;
- Facilitating access to investigational medical products for patients with Ebola, when requested by clinicians;
- Authorizing the use of seven diagnostic tests for Ebola under our EUA authority; and
- Actively monitoring for fraudulent products that claim to diagnose, prevent, or treat Ebola infection and taking action, as warranted, to protect public health (for example, FDA issued Warning Letters to six firms marketing products that claim to prevent, treat, or cure infection with the Ebola virus).

FDA's increased engagement under the MCMi has also helped to resolve many challenges and impediments associated with the U.S. Government's medical countermeasures pipeline so that development programs continue to move forward. For example, this has resulted in the approval of several medical countermeasures, including a therapeutic for inhalational anthrax, a botulism antitoxin, two antibiotics for the treatment and prophylaxis of plague, and a next-generation portable ventilator. Of note, FDA was able to approve the anthrax therapeutic for use in children as well as adults, despite the fact that pediatric patients were not studied due to ethical concerns during the development of this product. This achievement was made possible by the application of regulatory science.

FDA has also continued its efforts to support the establishment and sustainment of an adequate supply of medical countermeasures. For example, FDA supports the Shelf Life Extension Program (SLEP), a Federal fee-for-service program, for extending the useful shelf life of military-significant and contingency-use medical products, including medical countermeasures that are owned by components of DoD or other Federal program participants, such as the Strategic National Stockpile (SNS).<sup>1</sup> FDA laboratory personnel test and evaluate drugs submitted for shelf-life extension to ensure stability and quality before a shelf-life extension is approved.

In addition, FDA has continued to work to ensure that the U.S. Government is as prepared as possible to rapidly deploy medical countermeasures when necessary. For example, FDA has readied stockpiled medical countermeasures for potential use under its EUA authorities against a diverse array of threats including smallpox, anthrax, and pandemic influenza.<sup>2</sup>

<sup>1</sup> SLEP is designed to defer drug replacement costs for date-sensitive stockpiles of drugs by extending their useful shelf life beyond the manufacturer's original expiration date.

<sup>2</sup> To facilitate the issuance of EUAs, FDA has developed a pre-EUA submission process. FDA works with product sponsors or government agencies, such as CDC and DoD, to develop pre-EUA packages that will form the basis of an EUA request and decision, when circumstances justify. Pre-EUA packages contain data and information about the safety and efficacy of the

In the area of pandemic influenza preparedness, FDA has approved several influenza diagnostic tests, which can help facilitate an effective response to an influenza pandemic by rapidly identifying infected persons and facilitating appropriate containment measures and clinical care. In addition, FDA has approved several seasonal influenza vaccines, which helps increase and sustain pandemic influenza vaccine production capacity, including the first seasonal influenza vaccine licensed in the United States, produced using modern cell culture techniques, and the first seasonal influenza vaccine made through recombinant deoxyribonucleic acid (DNA) technology. Both of these vaccines offer an alternative to the egg-based process and a potential for a faster manufacturing startup in the event of a pandemic. FDA also approved the first adjuvanted influenza vaccine for use in people 18 years of age and older, who are at increased risk of exposure to the avian influenza H5N1 virus subtype contained in the vaccine. This vaccine is not for commercial distribution but will be part of the national stockpile in the event it is needed. Furthermore, FDA has collaborated closely with BARDA, the National Institute of Allergy and Infectious Diseases (NIAID), and CDC on developing avian influenza H7N9 virus vaccine candidates.

Additionally, FDA has approved the first intravenous antiviral drug to treat acute, uncomplicated influenza infection in adults and has expanded approval for use of an influenza antiviral, oseltamivir, to treat children as young as 2 weeks of age. Prior to this action, oseltamivir was only approved to treat influenza in children ages 1 year and older. FDA was able to expand the approved use of oseltamivir in children younger than 1 year old based on the extrapolation of data from previous studies of adults and older children, and additional supporting studies sponsored by both industry and academic researchers.

Consistent with the President's September 18, 2014, Executive order and the national strategy for combating antibiotic resistant bacteria, FDA is working hard to help ensure the development of new products in preparation for threats from naturally emerging infectious diseases from antimicrobial-resistant pathogens. Toward this end, FDA will evaluate new antibacterial drugs for patient treatments, streamline clinical trials, help phaseout the use of medically important antimicrobials in food-producing animals, develop better vaccines for antibiotic resistant organisms, and strengthen capacities to detect antibiotic resistance.

On the regulatory science front, FDA has established a broad and robust portfolio of cutting-edge research under MCMi's Regulatory Science Program to help develop the tools necessary to support regulatory decisionmaking. A few examples of ongoing projects include supporting the Wyss Institute for biologically inspired engineering at Harvard University as it develops models to assess radiation damage in lung, gut, and bone marrow, and then using these models to test candidate medical countermeasures; collaborating with DoD and the National Center for Biotechnology Information to establish a publicly available, well-curated, high-quality, whole microbial genome sequence reference data base from clinically important pathogens, which diagnostic test manufacturers will be able to use to advance their sequence-based test development programs; and examining the scientific basis for the instability of the protective antigens that has hindered efforts to develop next-generation anthrax vaccines and using protein engineering to stabilize the antigen.

#### CONCLUSION

Developing and enabling ready access to medical countermeasures to mitigate CBRN and emerging infectious diseases is highly complex. Close cooperation and collaboration within FDA and with U.S Government, international, and private sector partners are essential, and without this cooperation and collaboration, progress to address this growing public health challenge would be very limited. The deep engagement that is evident among the agencies represented here today is an example of public health synergy at its best. FDA is fully committed to continuing to work closely with our partners, using our authorities to the fullest extent possible to protect and promote public health, both domestically and abroad, in response to public health threats.

Thank you and I am happy to answer your questions.

Senator BURR. Thank you, Dr. Borio.

Let me say to all of our witnesses that as I look at the response and our capabilities over this period of time that we're looking at,

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product, its intended use under an EUA, and information about the potential emergency situation that might unfold.

we've gotten better every time. The level of cooperation that exists interagency is remarkable compared to where it was at the start.

I think that we have tried to work with every agency to identify those impediments that either needed a push or a legislative remedy to overcome, that stood in the way of either further collaboration or a quicker response or a more effective outcome. I plead with all of you if there are additional things that you see, having just, hopefully, gone through the Ebola—this version of the Ebola crisis—I don't want to be presumptuous—that are further changes that we need to make, then, by all means, make sure that we're fully briefed on what they are.

Our attempt is to continue to refine the legislation so that not only is it seamless, but it is the most expeditious that we possibly can present. I understand, especially to Dr. Borio, that there's a huge difference between your mission and Dr. Robinson's mission from a standpoint of core responsibilities of the agency. All of them have to work together for us to maximize the outcome, and that's what we're all after.

Dr. Lurie, one of ASPR's duties, as set forth by the law, is to provide leadership in international programs, initiatives, and policies that deal with public health and medical emergency preparedness and response. Yet over the past year as the Ebola outbreak grew in urgency and attention, the question of who's in charge was once again raised.

I'll ask you what specific steps are you going to take to make sure that the role of the ASPR is clear and fulfilled consistent with the statutory intent so that there is no future confusion on who is in charge?

Dr. LURIE. Thank you, Mr. Burr. I appreciate your question. I also appreciate all of your letters over the last few months to be sure that we, in fact, remembered our authorities and were in a position to leverage every single one of them that we needed to leverage for Ebola, and I believe that we did.

I'll answer your question in a couple of ways. To begin with, within ASPR, we have a group that very specifically deals with preparedness for international public health emergencies of different kinds—our collaboration with other countries were the focal point for the international health regulation reporting and others. We are positioned very much at that interface.

Within the department, as this unfolded, as I think you know, it unfolded first as a global or an international event in West Africa. I'll say for starters that if anyone ever needed any reminding that what happens somewhere else is important to U.S. domestic national health security, I hope they need to look no further than this past year as any reminder for that.

In a complex emergency where multiple departments and agencies are involved, as you first know, the President is in charge, and within the department, the Secretary is in charge. Throughout this event, the Secretary took full advantage of all of the different kinds of roles and expertise at CDC, at NIH, at FDA and ASPR and BARDA and beyond, pulling together people every day.

Senator BURR. Let me stop you there, if I can.

Dr. LURIE. Yes. Sure.

Senator BURR. Because there was tremendous thought put into this as we constructed it originally. As a matter of fact, you couldn't find anybody to raise their hand and say "I'm in charge" when there's a problem.

Dr. LURIE. I'm in charge.

Senator BURR. We created the office specifically for this purpose. Trust me, I get it. The President is in charge. When you get past the President—do you remember the weeks and months that we went through of the requests by the public and people abroad and people in government going "Who's in charge?" There was a point that the White House got to where they appointed somebody who never made a public statement, and they said, "You're in charge."

When I called the White House and asked who was in charge, they told me another person. The statute of the law says you're in charge, because you're ASPR. Why was that so difficult for people to understand? One of the purposes of this whole legislation was to map out what we do when something happens. Quite frankly, we got from there down pretty good, and this is not critical of you, individually.

I have raised this with the Secretary. I have raised it with the chief of staff at the White House. I have raised it with Lisa Monaco. We tried to recreate a wheel when we had an architecture in legislation already in statute that says if something happens, here's what we do—bam, bam, bam, bam, bam. It disturbs me only from this standpoint, that every other mechanism that we put in place worked almost seamlessly.

We could make the case, Robin, that maybe we should have had some stuff in NIH at a more mature state so that there could have already been a handoff.

I think, Dr. Fauci, you would probably agree with that. It got put on a back burner.

It might be that CDC might have had more assets prepositioned somewhere in the world, but they responded to it. It may have been that maybe FDA had done further thought about how do we expedite a review on things that are critical to whether somebody lives or dies. They've done that.

I still get the impression that we're not sold on who's in charge. What does it take?

Dr. LURIE. I take your point, and, as you know, we are not totally through this event. We still have a lot of action going on in West Africa. We hope we don't have more Ebola cases here, but we are focused and vigilant and prepared.

Even though we're not yet through, we have already begun both a series of in-process progress reviews as well as a process for us to step back and look at lessons learned and take corrective actions, both within the department, and I think it's fair to say that every part of government that was involved in Ebola is really looking at lessons learned and how to do better the next time. I will look forward to sharing those and discussing those with you as we move forward.

Senator BURR. Well, I hope you will also raise your hand and say, "You know what? I was supposed to do all this." As you know—

Dr. LURIE. Absolutely. I hear you.

Senator BURR [continuing]. I think so much of the Secretary. The Secretary, by design, wasn't put in charge, because the Secretary has all sorts of other things. For this, to at least be tried, we have to get to the point where we execute what the statute of the law says. I thank you for the work that you do.

Senator Casey.

Senator CASEY. Thanks very much, Mr. Chairman.

I wanted to start with something that I could have mentioned in my opening, but we've got two panel members that have Pennsylvania connections. The committee, I'm sure, will indulge me.

Dr. Lurie, as Senator Burr introduced you—both college and medical school at the University of Pennsylvania. I want to note that for the record.

Dr. Borio—senior associate at University of Pittsburgh Medical Center for Biosecurity and assistant professor of medicine at the University of Pittsburgh from 2003 to 2008.

I just had to say that, and I'm sure Dr. Robinson and Dr. Redd would want to retire in Pennsylvania or have some connection so we can mention it at a hearing.

[Laughter.]

I wanted to focus initially on one broad topic as it relates to all of your mandated responsibilities and the obligation you have to implement the Preparedness Act, including both the original act and then the new reauthorized act. I want to talk about children in a broad-based way.

A lot of great advocates for children over many years have often said that children are not small adults, that we have to often have different strategies, different approaches, and different treatment regimens to deal with the impact on children when we have a disaster or an outbreak. In particular, I wanted to ask each of you—and maybe just starting with Dr. Lurie and go from my left to right—to ask you how are you ensuring in your work that the needs of children are being met—and I know, Dr. Lurie, you mentioned children in the opening part of your testimony and it's in your prepared testimony.

How do you ensure that the needs of children are included in both preparedness and in terms of response planning efforts?

Dr. LURIE. Great. I'm so glad you asked the question. I came into this job, No. 1, as a mom, and No. 2, recognizing that children are a quarter of the population, and they're a very diverse population, and the area of children is an area that I feel very, very proud of our progress.

Let me just give you a couple of examples. To start with, we now have something we didn't have before, which is that all of our national disaster medical teams are pediatric-equipped and pediatric-capable. We took a look at where we were in terms of mental health in response and realized that we really fell short, in general, and fell short for children, and we've remedied that situation.

With regard to countermeasures, we took——

Senator CASEY. Let me just stop you there. Remedied in what way?

Dr. LURIE. Well, first of all, we have a formal operational plan now for how we do this, and we have formal components, formal guidance, and staff that deal with children. We took a good hard



look at our countermeasure portfolio and both put together an ongoing pediatrics-obstetrics group to look at countermeasures, but, more importantly, made specific countermeasures and formulations for children, both for the stockpile and for products in development.

These are anywhere from kinds of flu vaccines to radio-nuclear countermeasures and antibiotic formulations, all the way to a portable ventilator that is suitable for neonates.

We have a children's advisory committee now that just got up and running. One of the things I asked them to do first off was take a look at the issue of children at large and help us think about, No. 1, all the areas where children are not small adults, but also areas in which children, particularly youth, are poised to contribute to preparedness and response in a variety of different ways, because, as you know, we have to meet kids where they are along the whole developmental spectrum.

And, finally, just let me say with regard to Ebola, one of the things I went way out of my way to do was to be sure that we had children's hospitals that were prepared and will be funded as Ebola treatment centers. That's just a quick smattering. I could go on with a long list. I'm happy to provide more information.

Senator CASEY. I appreciate that.

Dr. Robinson and the rest of the panel, you're left to speak in sound bites now.

Ms. ROBINSON. In addition to the medical countermeasures that Dr. Lurie mentioned, we actually have pediatricians on staff that are able to help us with those medical countermeasures and work with FDA and CDC and ASPR on that.

Senator CASEY. Thanks.

Dr. REDD. In the strategic national stockpile, we include formulations that are specific for children, for example, oseltamivir suspension.

Senator CASEY. Doctor, when you say formulations, explain what that means.

Dr. REDD. It's essentially the form that the drug is stored in. It's as a suspension so children don't have to be able to take tablets or capsules. We have a children's team when we respond in the emergency operation center, and that is linked tightly with the American Academy of Pediatrics.

We also understand your question. In fact, we have a monthly public health grand rounds, and the one in March, this coming March, will be on issues for children. In fact, Dr. Lurie will be a speaker at that grand rounds.

Senator CASEY. Thank you.

Dr. Borio.

Dr. BORIO. In addition to what was already previously said, we also have a pediatric action team that works in tandem with BARDA to provide input on these issues, and I think that in the last 5 years, we've seen tremendous progress in the capability to develop and make sure that new countermeasures that are being approved today carry the pediatric indication. Even sometimes when studies cannot be done in pediatric populations, we'll use regulatory science to be able to extrapolate a dose, given the important need of children during disasters.

Senator CASEY. Thank you very much.

Thank you, Mr. Chairman.

Senator BURR. Chairman Alexander.

The CHAIRMAN. Thank you, Senator Burr.

To all the witnesses, we have an ongoing priority in this committee, a project on innovation to try to identify how to move treatments, cures, and devices from early stage development into medicine cabinets, and to do that more rapidly and still do it safely. We're doing that in a bipartisan way.

We're doing it in parallel with an effort in the House called 21st Century Cures. President Obama is very interested in it because of his interest in precision medicine. I've talked with him about it.

What I'd like to say to the four of you and to your agencies is that the train is moving through the station this year. We expect to finish that work this year. We already have a bipartisan working group of staff members that Senator Murray and I have constituted.

If there are specific legislative things that you need us to do, now is the time to do it. We need specific recommendations.

For example, Dr. Borio, if you need new tools to develop medical countermeasures that we've overlooked, I wouldn't wait a year or two. I would offer suggestions within the next few weeks.

I think we will succeed with this. There's no reason we shouldn't because of the broad interest and support we have both from the administration and from the Democrats and Republicans on the committee.

I have two questions I want to ask, but I want to go back, Dr. Lurie, to this "who's in charge" question. When I was a Governor, I used to have a phrase, "Who's on the flagpole?" If nobody was on the flagpole, nothing got done. If somebody was on the flagpole, usually we'd show up the next week and it got done, because it would be that person's responsibility.

I think of Hyman Rickover, who would tell the captains of the nuclear subs two things when they'd have a 7-minute interview with him. One is, "You're in charge of the ship. You're in charge of the reactor. If anything happens to the reactor, your career is over." We have never had a death as a result of a Navy reactor problem in the last 60 years in this country because of accountability.

We didn't have that with Ebola. Maybe it was our fault for not seeing it. I expected someone to step up and say who was in charge and maybe this is the President's fault. Somebody should have said, "Dr. Lurie is in charge here. She's on the flagpole." If it had been a military operation, we would have had a daily briefing.

We had a near panic in the United States over Ebola. I thought for a while that if I had announced, or if you had announced, that if you'd take your flu shot, you wouldn't get Ebola, about 9,400 lives could have been saved, because people would go take a flu shot, an Ebola shot, because people were so afraid of Ebola.

In Tennessee, public health departments were turned upside down because all they were doing was Ebola. In hospitals, they were spending all their time and money buying personal protective suits for Ebola. All that was good, and the reaction was good. It needed to be put in perspective, and people were afraid.

I think we should consider if the Assistant Secretary of HHS can't be seen in an epidemic as in charge, then maybe we should change the law. I know you have thought about this.

First, it was Dr. Frieden. Next it was NIH. Then the President appointed a czar who became the phantom of the White House and disappeared and was never seen again. Maybe he did a good job, but none of us would know it. He wasn't available to testify before this committee or any other committee because he was a White House czar. This is something we should think about before we have another incident like that.

Let me go to you, Dr. Robinson. I visited Dr. James Crowe at Vanderbilt University. He's developing antibodies for Ebola—one of the most advanced centers for that kind of work. It was very, very impressive. He did some of the work with Mapp Biopharmaceutical that has been mentioned.

He talked about the "Valley of Death," and his antibodies for Ebola are many years away from being available to help cure someone. What else can we do about the so-called "Valley of Death," which is generally described as the space between studies in the lab and human clinical trials? How can we compress that, both for identified threats and emerging threats, like—Dr. Crowe was working on something called chikun.

Ms. ROBINSON. Chikungunya.

The CHAIRMAN. Yes. That's not an identified threat. That's another one of these things that could come at us from out of left field, and it's not even in line with an identified threat. What else can we do about the "Valley of Death?" I'd conclude by saying again if there are legislative things we need to do, this year is the time to do it.

Ms. ROBINSON. Thank you for the question. There are two things I would say. First is that BARDA has been able to mature programs for CBRN and pandemic influenza. The third part of what PAHPA put us in charge of doing was making medical countermeasures for emergent infectious diseases.

We haven't until the Ebola epidemic actually been able to really get into that space. We now are fully there with all our response capabilities and everything that we've done for the others. We are setting up an emergent infectious disease division that will have response and preparedness responsibilities, and we need to be able to afford to do that and prioritize those high threats for emergent infectious diseases to do that.

The second thing is our Centers for Innovation in Advanced Development and Manufacturing were for advanced development. What we had to do because candidates were so early in development—we had to reach back very early. We realized that's something that we do well and we can go forward with in actually being able to take, with response capabilities, early development, even almost discovery, and bring them forward.

We did this with Ebola monoclonal antibodies with several companies starting from scratch, and they were able to do it in 4 or 5 months. Now we're being able to go into non-human primate studies, and we'll be going into clinical studies later. We can do that, but we need to be able to have the resources to do so.

Senator BURR. Senator Warren.

## STATEMENT OF SENATOR WARREN

Senator WARREN. Thank you, Mr. Chairman. Infectious diseases pose an enormous threat to human health and to the world economy. Each time a disease appears, Congress is great about spending billions of dollars combating the immediate crisis. But Congress is terrible about spending money to make sure we're ready for these crises before they occur.

NIH funds the research that leads to the cures, but it has lost nearly 25 percent of its purchasing power since 2005. The CDC is responsible for keeping us safe from outbreaks, but Congress gives CDC only about \$20 per American to be prepared for everything from a bad strain of the flu to food poisoning to Ebola. Project BioShield, which ensures that we have medical countermeasures for emergencies, is subject to the tumultuous appropriations process.

What I'd like to ask is how do robust and stable investments in basic research and development help us prepare our Nation to deal with known and unknown contagious diseases? Maybe I could start with you, Dr. Lurie. If we can, we'll try to keep this short. I want to make sure we get this on the record.

Dr. LURIE. Sure. Thank you so much for your question. It's terribly important. One of the things that's so challenging is that Americans forget quickly, and we do lurch from crisis to crisis. The funding lurches from crisis to crisis.

We need to have sustainable funding that people can count on year after year so they can hire employees, so they can make investments, so they can continue to train and exercise. I know that, initially, Project BioShield was a 5-year commitment. We've moved to an annual appropriation. I understand that the annual budget cycle sometimes is not exactly what people need to have reliable, sustainable investments.

I think it's worth taking a look at how we fund preparedness overall, both the research and development and countermeasure parts, but also the routine public health emergency preparedness, hospital preparedness, which has had significant cutbacks as well, and to be sure that a workforce coming up in this field who want to dedicate themselves to America's health security know that this is a sustainable career path and the rug isn't going to be pulled out from under them as soon as they train.

Senator WARREN. A very important point. Not just the training of the current workforce but how we develop the people who are going to do this work.

Would you like to add to that, Dr. Robinson?

Ms. ROBINSON. Yes. Thank you. I think that Project BioShield with the addition of PAHPA made the advanced research and development pipeline very robust, and now we're ready to go forward and harvest some of that fruit. Without having sustainable funding going forward, then our partners in industry are really at a standstill as to whether they should continue with their portion of the funding going forward.

Project BioShield was funded under the special reserve fund originally under a special appropriations. Industry has asked for that, and, certainly, we wanted that to begin with. We understood

budget austerity, but we still think that that's an important message.

Senator WARREN. If I can say it another way, we get maximum leverage from the Federal dollars by getting the industry to pick up much of this work. That happens better when there is robust funding that's guaranteed over a much longer period of time.

Ms. ROBINSON. I agree.

Senator WARREN. Is that fair?

Ms. ROBINSON. I agree.

Senator WARREN. Good.

Would you like to add to that, Dr. Redd?

Dr. REDD. Yes, ma'am. What we find in emergency response is that the public health systems that are in place all the time are the ones that are most able to adapt to be used for an emergency response. I'll give you a quick example. During the H1N1 pandemic, we distributed the monovalent vaccine through the system that's used to send vaccines into the Vaccines for Children Program. It worked very smoothly. Physicians were able to order doses through their health departments.

In contrast, the system that was used to distribute oseltamivir delivered it to States where there hadn't been the same kind of planning and experience in distributing that drug further down the line, and it didn't work as well.

Senator WARREN. The short version is we've got to be ready all the time. Right?

Dr. REDD. Yes, ma'am.

Senator WARREN. All right. Good point, Dr. Redd.

Dr. Borio, would you like to add anything?

Dr. BORIO. Thank you for the opportunity. Our resource requirements are of a different magnitude because we are not developing and purchasing products. For the health of the pipeline, the FDA plays a very critical role. Our expert staff and our regulatory science need to be supported to be able to support the entire pipeline.

This staff that works in these areas are highly, highly expert and experienced. We need to be able to hire and retain them.

Senator WARREN. All right. Thank you all very much. We're falling behind in our preparation for known threats, and we're not laying the intellectual and the scientific groundwork to prepare for the next round of threats.

If Congress is truly concerned about the very real threat of contagious diseases, then we need to start making some smart decisions right now, and that means supporting basic research at NIH. It means supporting preparation by CDC, and it means supporting long-term planning by BARDA. We spent decades building these agencies, and now it's time for Congress to step up and make sure they have the resources that are necessary to protect us from the next biological threat.

Thank you, Mr. Chairman.

Senator BURR. Thank you, Senator Warren.

Senator Cassidy.

## STATEMENT OF SENATOR CASSIDY

Senator CASSIDY. Dr. Borio, during the Ebola outbreak, several agencies, including USAID, the Defense Threat Reduction Agency, issued broad agency announcements seeking proposals for devices and diagnostics to respond to and contain the Ebola outbreak. Did the FDA implement an expedited approval process for these devices? How long would the expedited review process take, if they did? And can the FDA trigger it with existing authority, or do you need specific requests from another Federal agency?

Dr. BORIO. Well, our outreach in the diagnostics has been one of the most active. As a result of PAHPRA authorities, we've been able to issue EUAs for now eight diagnostic tests.

Senator CASSIDY. So your existing authority is adequate?

Dr. BORIO. Yes, and our staff basically stand ready to review submissions as they are received. As an example, the first test for Ebola that was authorized for use under an EUA was a DoD developed test. We were able to authorize it within 24 hours. The most recent EUA was issued after staff on standby worked through the weekend to review the application.

Senator CASSIDY. Well, a hat tip to you all for being so prompt. Thank you, and I mean that sincerely.

Dr. BORIO. Thank you.

Senator CASSIDY. Dr. Redd, March 2014, Guinea had reported—as I review the literature, I think it was back in Zaire long ago that there was an outbreak of Ebola that was contained, and we knew how to contain it. In March 2014, Guinea had reported 49 cases—which within weeks spread to Liberia.

I remember seeing an MMWR report on this, and sometime—I couldn't dig it back up, but sometime early summer, CDC had field workers in the affected countries. You all were aware of this and were in the process of responding. It wasn't, though, until the cases reached the thousands and Americans were getting infected that we really triggered that huge response.

You all mentioned that you are doing kind of a postmortem. I don't mean that in a grisly sense, but, a kind of after-the-fact analysis of what's going on. It begs a question, though. You've got trained public health there. You know how to stop it, but you see the genie coming out of the bottle. Why did it take this sort of dramatic increase before the hammer went down and those resources were fully requested?

Dr. REDD. Yes, sir. The outbreak was identified in March 2014. A large team responded to that, a multinational team led by the World Health Organization. The disease was brought under some measure of control, but not enough. The entire team redeployed in May–June, and—

Senator CASSIDY. Wait, there's something you left out. Redeployed—meaning they were yanked out?

Dr. REDD. They came back. Yes, sir.

Senator CASSIDY. What was the incident rate, and what was the geographic spread and the interval between when they were pulled out and it began to spread once more?

Dr. REDD. I can get you the exact numbers. I don't have those on hand right now, but I think I would take your main point that that was a mistake.

Senator CASSIDY. It's easy with a retrospective to look back and say it was a mistake. Reasonably speaking—again, I'm asking, because CDC—you're good. You're real good. You had—no, wait a second. There's a case over here that previously has not been contained. Maybe we should not pull out. Did you have the ability to not pull out if World Health said "yes" but you said "no"?

Dr. REDD. I think in retrospect, we would not have pulled out. Let me just continue on, because the emergency operations center at CDC was activated at the beginning of July, and that was as cases in Liberia and Sierra Leone were detected. We've been activated since that time, our highest level of activation since early July. Cases really—there was an exponential increase that began in August and September.

Senator CASSIDY. The exponential increase—just intuitively, you know that there was a slope that began to ascend, and this is a curvilinear slope, so it's going to begin like that and then it's going to rocket-ship up. Right?

Dr. REDD. Yes, sir.

Senator CASSIDY. I guess the question I come back to—Senator Alexander has left—but it seems like there should have been somebody on the ground, saying, "Listen, we're seeing a curvilinear increase in the number of cases. This thing is about to take off." It shouldn't have taken an American missionary to get infected. Do you follow what I'm saying?

Dr. REDD. I do. I do. Actually, I wanted to say that the recognition of the problem did not coincide with the people coming back with infections. It was before that—

Senator CASSIDY. Well, believe me, I understand that. You guys are so good. You saw that graph, that incident rate, beginning to increase, and that begs the question, though: Did it fall on deaf ears? Did people there make a mistake in not asking for more help? Because there was a critical time where you could have stopped it, and yet it took off.

Dr. REDD. I think that there was a period in May and June when a more vigorous response could have made a big difference.

Senator CASSIDY. Again, I come back to my question, and maybe you can't answer it. Were the resources requested and not given? Or were the resources not requested?

Dr. REDD. In July, when we went back in, we recognized that there was a problem. The actual request for large resources—and I think probably the full recognition of the problem—was not until September. That was when, as you'll recall—

Senator CASSIDY. August is when the exponential increase began. Did I hear that correctly?

Dr. REDD. There was a lot of work trying to figure out what was going on during that period of time.

Senator CASSIDY. You're not answering my—I don't mean—

Dr. REDD. Well, I'd say that I think that the period when the exponential increase was recognized was in early September, and the resources were requested shortly thereafter.

Senator CASSIDY. The American returned in August, and that's when I think it started garnering a large amount of attention. I assume there was a death rate. You could just look at the Liberia version of an obituary and have a sense of the death rate. It was so deadly.

I guess what I'm not fathoming is since your death rate is such a ready indicator of something bad happening, your death rates increasing—I don't understand the lag time between requesting additional resources and the body bags filling up, so to speak.

Dr. REDD. Well, all I can say is as soon as we recognized the extent of the problem, we began to work harder and to try to define what resources were going to be needed. As soon as that request was formed, it was made.

Senator CASSIDY. OK. I yield back.

Senator BURR. Thank you, Senator Cassidy. Let me—I'll wait for Senator Franken to come back, but I'll take some time in the interim.

In fact, to Senator Cassidy's answer, Dr. Frieden went in August, and when Dr. Frieden came back, all of a sudden the request was made.

Dr. REDD. Yes, sir.

Senator BURR. I mean, it triggered the director being on the ground. It triggered somebody in that multiple leadership level—and I'd go back to Dr. Lurie. That's why it is so important that there be somebody driving the train.

I guess I would ask this, Robin. When did the vaccine alarm bell go off?

Ms. ROBINSON. Last summer, probably the middle of the summer, because we had been looking at a number of different candidates at the NIH, also at DoD, and we went out and immediately started looking at procuring those for development. NIH and CDC were moving forward with putting together the initial clinical trials with Walter Reed, which actually started in September and in October, and we made investments at that time, not only in vaccines, but also in August, in fact, we went forward with ZMapp as a major investment for countermeasures.

Senator BURR. I want to point out that this is why we know what we had in place works, because the alarm bell went off for vaccines before Dr. Frieden was on the ground, before the request.

Dr. Lurie.

Dr. LURIE. Yes. Let me provide a little bit more information about timeline and some activities.

Back in the spring, as we saw the epidemic unfolding in Liberia, one of the things that I did was pull together all the members of the Countermeasure Enterprise, including all of HHS, DoD counterparts, DHS counterparts, others, and said, "What do we have anywhere in the pipeline? What's buried in there? Let's talk to our international partners."

Through that, we identified the two vaccine candidates. We identified ZMapp and some other candidates, and we had a number of Enterprise meetings and said, "What is it going to take to put our foot on the gas, pick who we think we can get—the candidates we think we can get forward with faster?" By the time that we really sounded the alarm bell, there was already a huge amount of work



in progress, because now the Countermeasure Enterprise is working together so well.

I will comment—I'm sorry Mr. Cassidy is not here to do this. Throughout this whole Ebola episode, we have been racing to catch up with FDA. They have been amazing in their speed and their flexibility and their real outreach to work with companies.

Similarly, back in the spring/early summer, as we looked at the Ebola trajectory, we said, "We need to start waking up our U.S. healthcare system and preparing them," and began working with CDC to develop and push out lots of guidance and information. In fact, while this was still in Africa, and the epidemic curve was still going up, Dr. Frieden was on the ground.

We were taking many, many steps here in this country to advance our preparedness and to get the countermeasure work going. That's, in fact, why we've got two vaccines in clinical trial right now in West Africa and a ZMapp trial which will start any day.

Senator BURR. I'm not going to be as diplomatic as Senator Cassidy was, because I think what he was alluding to—and I'm not surprised you won't go there—was the WHO an impediment? I'm not asking you. I don't want you to comment on it. The fact was that the WHO was the lead on the ground, and CDC, even with great insight as to what the potential was down the road, wasn't in a position to make a decision to trump the World Health Organization.

The reason I'm less diplomatic and go ahead and mention those three letters—folks, this is something we have to think about. I can't tell you how many times I was on the phone, saying, "Forget about them. Bypass them."

When we see the threat as seriously as we did, then we have an obligation to this country to do whatever we need to do in conjunction—and I think this is where we ended up—with the countries affected and not with some health architecture that probably had never modeled something quite like this. I only hope that this is one of the discussions internally that we will have: How do we react next time if, in fact, we run up against an impediment that looks like this?

Let me just move very quickly—Dr. Borio, as you know, human efficacy studies are not feasible for some medical countermeasures. Therefore, FDA's animal rule is particularly important for such products. The 2013 PAHPA reauthorization required FDA to finalize guidance on animal rules.

We're coming up on the 2-year anniversary of the enactment of PAHPA, and this final guidance is already past due. When will the animal rule guidance be finalized as required by law?

Dr. BORIO. Senator Burr, first I'd like to thank you for bringing this issue up, because I share your sense of priority for the animal rule, and I sense the frustration for this animal rule guidance not having been completed as of yet. We did issue the revised guidance in May 2014. The comment period closed in August 2014.

I don't mean this as an excuse, but we have been very engaged with stakeholders on the guidance, as well as providing some additional training, and the feedback we have received is overwhelmingly positive. Having said that, I also requested a timeline and additional action items that are required to bring this to closure, be-

cause, again, I share your priority, and I'll do everything I can to bring this to closure as soon as possible.

Senator BURR. I appreciate that. Please carry the message back that we are watching. My only regret here is that it doesn't take EPA as long to promulgate rules and to put authorizations out as it does at FDA.

Dr. Redd, less than 24 hours before today's hearing, CDC updated its website to include information on the influenza antiviral that was approved over 2 months ago and is highlighted in FDA's testimony here today. This countermeasure was supported by BARDA and played a role in the H1N1 response. I'm concerned that in the midst of one of the worst flu seasons in recent memory, it took CDC more than 2 months to update its website. What took so long?

Dr. REDD. Sir, I can't answer that question directly. I can get back to you with an answer. I think 2 months is a long time.

Senator BURR. Well, let me say get back to us with an answer and also what steps, if any, is CDC taking to ensure that this type of delay in providing the most up-to-date and complete information to healthcare practitioners, whether it's in the midst of a flu season or not—it could be an emerging threat like Ebola, and this would seem like it's a fairly easy thing to try to accomplish. So please take that back.

Senator Casey.

Senator CASEY. Thanks, Mr. Chairman. I wanted to get back to a broader question, make a brief statement and then go to some followup questions.

The urgency that Senator Burr is talking about is essential and not just in the heat of the challenge or the crisis. We've got to have a sense of urgency that's maintained month to month, year to year, long before we face that challenge.

I was not at all satisfied in the initial weeks, of the Ebola outbreak, with how the administration was communicating about this. I just thought it wasn't where it needed to be. That was unfortunate. I hope, not just this administration, but a lot of folks can learn from some of the shortcomings of the response.

Doctor Lurie, when you have a title like yours, Assistant Secretary for Preparedness and Response, I think it's critical that that be made known quickly, and that people in the administration, or the next administration, or 20 years from now—that they identify you as the point person, and that that's very clear. I think the communication has to be much clearer.

Having said that, there was a problem at the time this was playing out, in my judgment. It is my opinion that because you had the combination of some shortcomings on communication combined with a political season, and then the third element, unfortunately, was some irresponsible statements by folks here in Washington—I won't say who, but a few Members of Congress—that added to the problem. That's just my opinion.

I was asked at the time what should be the response from Members of Congress in the midst of a crisis like that. Unlike Senator Burr, some Members of Congress weren't looking at science, and they weren't looking at constructive proposals. I came up with a

radical idea that Members of Congress should make constructive proposals based on science. I hope we can do that next time.

Along the way, Senator Warren's point about funding is very important. I really am grateful for the way in which Senator Burr has engaged with me on preparedness issues, and also with other members over many years. I think we can all be better prepared next time. Even though I think the results by and large were positive, when you look at what happened here and what could have happened, it could have been a lot worse than it was.

Let me just ask you, Dr. Lurie, you don't have to agree with my assessments—but if someone walked up to you, or to me—let's say I'm walking down the street in Pennsylvania, and someone says,

“Well, look, generally, I think we were pleased with what happened, and that we didn't have the kind of horror that we saw in West Africa, but I'm a little concerned about how we dealt with it.”

What would you say to that constituent of mine when they said,

“What did you learn? What did we do well? What needs improvement, and what are the areas where Congress can play a more constructive role?”

Dr. LURIE. Great. I appreciate you asking that question. I would agree with your constituent that, certainly, early on, it was pretty bumpy. There were some missteps. I think we were all able to pivot and get ourselves on a good course. I think that's just how it was.

We're still in the process of learning lessons. I think there are a couple of things that are important to highlight now. We already talked about our interconnected world, but I do want to highlight that that's why funding for the global health security agenda, which really strengthens our ability to have good situational awareness and respond anywhere in the world, has been part of the President's fiscal year 2016 budget.

The other thing I'll say is when we have an emergency that doesn't invoke the Stafford Act, as we did with Ebola and as we have many times before, there are a lot of questions about where money comes from. We have not had—

Senator CASEY. Can you explain that so people understand what you mean.

Dr. LURIE. When the Stafford Act is invoked, then money is available through FEMA to respond, both federally and at the State and local level. When you have these other kinds of emergencies, largely when something doesn't go boom or terrible weather doesn't come through, we need to respond with the current appropriation that we have on hand. Usually that's already planned for and spoken for.

We don't have an emergency fund that we can turn to, to get going. We saw this very much in this event. Congress was terrific, you know, ultimately in providing this emergency funding. As you know, we all needed to start to respond both in West Africa and here long, long before that happened.

You'll see again in the President's fiscal year 2016 budget that there's a request for a sizable emergency fund that I think we all agree would sit there until there is the next really bad crisis. Then we don't have to wait for lots and lots of other processes to run

their course to find the funds to get going. That's important both at the Federal level and it's critically important for our State and local partners, who get asked to do a huge amount in these emergencies and, similarly, don't have the funding to hire staff or turn on the apparatus.

As a place where I think we could make some immediate improvements and from a policy perspective have a way to go forward, for me, that's probably No. 1. I think there are some other smaller things that you'll also find in the President's budget.

For example, we couldn't send our national disaster medical system responders into harm's way with Ebola because we had never been able statutorily to solve this issue about disability and death benefits should they get hurt or injured in service. Again, you'll see a proposal and request to do that in the President's budget.

I think at all three levels, the global level, how we respond nationally with immediate funding, and then at the smaller responder level, we all have identified already many steps to take to improve going forward.

Senator CASEY. I know we're over time, but does anyone else want to weigh in on lessons learned and what you hope we'd be able to do better together?

Dr. REDD. Just repeating Dr. Lurie's emphasis on the global health security agenda. Working with these countries bilaterally to develop the capability to detect, and once detection occurs to respond effectively could have stopped this problem long before it got to where it did.

Senator CASEY. Thanks very much.

Senator BURR. I think it's only appropriate while we're having this hearing that there is a news flash that an Arlington County individual has been taken by EMS—a potential Ebola case. We've been through that many times and found it to be not the case.

Dr. LURIE. This is a place, though, where the system now works extraordinarily well, and I want people to really understand that.

Senator BURR. I'm convinced it is, and I think, specifically, for you, I'll put this out as a thought. At some point, we're going to have to explain exactly how we came up with the hospitals designated to handle, because there are a lot of institutions out there that felt they should have been included in that. Maybe there are a lot that hoped that they'd never been included in it—I think that's a question for another day.

Given what we know today about the amount of contaminated waste that had to be delicately taken care of, when we say this hospital has the capacity for 10 Ebola patients or 10 infectious disease patients in the future, yet we look at the capacity to dispose of the waste, meaning two patients, haven't we done an injustice by suggesting we've got 10 beds when we've only got 2 beds that we can fill and adequately take care of? I know this is going to trigger a lot of things for you.

Dr. LURIE. It is, and I look forward to as wholesome a discussion as you would like about the strategy, about designation, and the way we've approached Congress' request to have a regional strategy going forward. I actually feel that it's quite sound.

Senator Casey really talked about the importance of science-based decisions. Clearly, at the beginning of this, there were some

things we didn't know about the science. It also got, as I think we've all pointed out, very confused with the fear and other factors.

Yes, a hospital that is an Ebola treatment facility has to be able to handle waste. We also know that there are facilities in this country that handle waste all the time, including things like deactivated chemical weapons from Syria or the Middle East, that were unwilling to take incinerated, not infectious ash from an Ebola patient.

We have to put some science behind this and some rationality behind this as we solve the problem. It's an area where my office has been working very closely with CDC, with EPA, the Department of Transportation, and we'll have some good solutions going forward.

Senator BURR. Well, I appreciate that, and let me just make this comment that I was telling Senator Casey when others were asking questions. I can still remember Senator Mikulski and I going through table-top exercises prior to writing the legislation and how many times we got to a point where you looked around the table and the question was, "Who's in charge?" Nobody had an answer to it. That's why most of what went into BARDA was the direct result of going through and gaming these things out and knowing the difficulty.

I hope that the after-action process that is initiated from this exercise in Ebola, regardless of which agency it's at, is that we're sitting down, taking those things that we now know are difficult, those things we now know are inciting for the public, and we're figuring out a way to structurally make sure that we've either minimized them or eliminated them for the next round of this, because that's absolutely important. I would tell you it starts right at the top, that somebody is securely in charge of the whole process right from the beginning.

Dr. LURIE. Yes, and let me make two comments. No. 1, that has already begun. I've taken responsibility for this review process. We already have a long list. Some of these corrective actions are already in progress, and I'm sure we will surface more along the way.

Senator BURR. Good.

Dr. LURIE. I also don't want to leave you or anyone else with an impression that this whole response hasn't been coordinated. I mean, I want you to be really——

Senator BURR. I feel confident that it has been. Please do understand——

Dr. LURIE. I understand.

Senator BURR [continuing]. That when I call six different places, one of them being the White House, and nobody can answer the question of who's in charge, I have every legitimate reason to sit up here and question at what point was there one person who was moving the pieces and making the requests. I'm hopeful we won't have that problem again.

Dr. LURIE. Yes.

Senator BURR. That was my most recent experience, and it became very personal, because I thought we did a very good job of stating in the statutory language exactly how it was——

Dr. LURIE. Because you are the poppa and the grandpoppa, yes.

Senator BURR. Robin, as you know, BARDA intentionally has a very specific and targeted medical countermeasure mission, and this is to ensure that BARDA is staying focused on bringing forward the medical countermeasures we need to protect the American people from a range of chemical, biological, radiological, and nuclear threats. The statute that governs BARDA is clear on the focus of this mission with all of BARDA's work being tied to this threat context.

I understand the concerns about increasing resistance to certain antibiotics. Just this week, there have been reports of an antibiotic-resistant superbug surfacing in North Carolina. Clearly, antibiotic resistance is a significant public health concern. However, I want to take this opportunity to clarify that BARDA's work in this area is tied to its overall work to advance medical countermeasures against CBRN threats and not outside of this context.

Would you please take a moment and explain why BARDA is working to bring forward broad spectrum antibiotics to address the CBRN threats we may face and why it's so important that BARDA's mission not be diluted by matters or mandates that would require BARDA to work on areas outside of those tied to threats we have discussed here today?

Ms. ROBINSON. Certainly. We have a material threat assessment and determination from the Department of Homeland Security that says antimicrobial resistance could occur in these biothreats, like anthrax. That is a threat for us, and that was the impetus for us in 2010 moving forward toward developing new classes of antibiotics that would be able to address antimicrobial resistance in biothreats.

I want to make really clear where we are on this. Our mission was primarily for biothreats. It will remain there with this development of antibiotics. They will have benefits for other high-priority community pathogens. In fact, we see one of the drugs that we have been developing, plicamycin, that has been working for a number of different biothreats, is actually being used—can be used for CRE and may be actually being used in the outbreak in UCLA hospitals.

Saying that, our funding for broad spectrum antimicrobials—because there are a number of those different pathogens that are biothreats—we want to make sure that we have coverage for those. There are several burkholderia species that cause glanders and melioidosis that—we have drugs, but they certainly could be made much better, and we want to make sure if they're wild type, not antimicrobial resistant—that we can address those wild type pathogens and have better drugs for that. That's the main impetus of this.

We certainly want to make sure that the benefits that we have in those investments can be made for multiple indications that can help public health, too.

Senator BURR. Dr. Redd, as you and your colleagues at CDC and BARDA know, it's very important to make sure that BARDA and CDC are coordinating on strategic national stockpile needs so that we're bringing forward medical countermeasure candidates that will meet the identified requirements. There are few mechanisms by which HHS can produce countermeasures.

For example, BARDA is responsible for executing the BioShield Special Reserve Fund, which is used to procure security countermeasures in the strategic national stockpile, and CDC also receives funding to manage the strategic national stockpile, including replenishing expired products.

How is CDC transparent to stakeholders regarding what opportunities may exist to be considered for the strategic national stockpile outside of the BioShield procured product?

Dr. REDD. Yes, sir. There are a couple of ways that we do that. First on the internal coordination, I mentioned the Public Health Emergency Medical Countermeasure Enterprise, where the strategic national stockpile budget is reviewed and recommendations are made. There's internal coordination, particularly between BARDA and CDC.

The multiyear budget that I believe this committee requested is part of making the future needs apparent, and I think that was just released within the last few weeks. That would be a way of forecasting what the future requirements would be.

Senator BURR. Let me ask you, how does the handoff occur for products that may have been procured or received from BARDA in advanced research and develop funding but are not procured by BioShield but could still be potential stockpile candidates?

Dr. REDD. I think, in general, when a product is licensed, it moves into the strategic national stockpile responsibility, and at that—there may be a first delivery through BioShield, but then it's transferred to the strategic national stockpile responsibility.

Senator BURR. Senator Casey.

Senator CASEY. I wanted to just note something for the record, but then ask one question about the Hospital Preparedness Program. The three countries that have had the most deaths from Ebola were, as everyone knows, Sierra Leone, Liberia, and Guinea.

Total deaths as of February 21 are 9,556, a huge number, and we are mindful of that today, especially in light of the fact that our country had a capacity and an ability that those countries didn't have.

Getting back to the circumstances here, one of the best things that the Congress did over the years was to not only authorize but fund the Hospital Preparedness Program.

Dr. Lurie, I meant to ask you earlier about the announcement that was made with regard to both hospital preparedness and the other program—the so-called PHEP, the Public Health Emergency Preparedness Program. Can you talk about the awards? I know that Pennsylvania got a little more than \$15 million allocated. Could you walk through that for us?

Dr. LURIE. Sure. The Public Health Emergency Preparedness Program is a program that strengthens the capabilities of health departments to do essential public health functions. It is administered at CDC, and I think to Dr. Redd's point, it's one of those things that builds the strong day-to-day system that we have to count on during an emergency.

The Hospital Preparedness Program is the part that funds the healthcare system administered through my office. We've worked very closely together over the past couple of years to align these administratively and in terms of the capabilities that we require

both from the public health system and the healthcare system. They're very efficient programs.

Having said that, if you look at the funding for these programs over the last decade and over the last X years, you'll see a steady decrease, and that gets to our point about always needing to be prepared and not having the sort of roller coaster shape to this.

With regard to this most recent funding, States put out a lot of money and need to continue to do lots of monitoring. The Public Health Emergency Preparedness money funds that. Senator Burr just talked about a suspected case in Virginia. That funds the State and local capability to deal with that.

The Hospital Preparedness money funds the capability to be sure that every hospital can recognize, detect, and safely isolate somebody until they're transferred, that there are hospitals that can assess these patients and decide if they have Ebola or not, and to the extent that somebody has Ebola, that those patients can be safely transferred to an Ebola treatment center for treatment.

Both Congress and our stakeholders gave us very strong advice about a regional strategy going forward. The announcement that just came out basically calls for 10 regional—I almost want to call them supercenters—but regional Ebola treatment centers, like Emory, like Nebraska, one in each HHS region.

Underneath that, all of the hospitals that have been so designated would be the surge capacity for those Ebola treatment centers regionally, so that we really develop these hospitals that are centers of excellence, so that if we have more Ebola, we'll really have a lot of experience with it. They'll be prepared to take care of more than one patient at a time. They are super-prepared for other kinds of infectious diseases, and they have to be ready within a matter of a few hours to take a patient, not to then have to spend lots of time tooling up to be ready.

I'm afraid Ebola could be with us for a very, very long time, which means that we are at risk here for a very, very long time, and we have to stay prepared and vigilant. We cannot let our guard down.

Senator CASEY. Well, I'll say just one thing in closing. I complain loudly and frequently and will continue to complain when you have an authorization level for hospital preparedness, your program under your jurisdiction, when there's a huge gap in the tens of millions of dollars between authorization and appropriation. It made no sense, and we'll continue to monitor that.

Dr. LURIE. I appreciate it.

Senator CASEY. Thanks very much.

Senator BURR. Thank you, Senator Casey.

Let me just add to what Senator Casey said, because he read the official death numbers. I don't think there's anybody at the table that believes that that is an actual number of how many deaths there were in West Africa, and the unfortunate thing is we may never know exactly the extent of this outbreak.

I'm going to recognize Senator Whitehouse for no more than 5 minutes.



## STATEMENT OF SENATOR WHITEHOUSE

Senator WHITEHOUSE. Thank you very much, Mr. Chairman. I appreciate it.

I guess my question is twofold. I have heard that when a biological agent is delivered in weaponized form at extremely high dosage—more than would occur in a natural propagation of the illness—the characteristics of the disease and the characteristics of its propagation change, that it's dosage sensitive in that sense. My first question is: Is that true?

The second thing is that I have heard that there are strategies for developing countermeasures that are more cutting edge than cooking them in batches, but that the technical effort to get there is lagging a bit, and that there may be a lot of incumbency pressure not to allow these disruptive technologies to emerge. I'd love to hear the witnesses' response to those two observations. Am I being given good info on those?

Dr. LURIE. Well, certainly, we always worry about weaponized forms of biothreats. That's, in fact, part of why we exist, that's why BARDA exists, and we take those things very seriously. It is very often the case that the more of something you're exposed to, and get in your system, the sicker you get. This is a really significant issue for us. We work on this issue all the time.

In terms of the disruptive technologies in innovation, a huge focus of our efforts is on innovation and on new and better ways to do things—faster, better, cheaper. Since the countermeasure review in 2010, we've moved away from one-bug-one-drug to platforms, to new technologies that can make countermeasures quickly, and we are always on the lookout for these.

There's a whole part of BARDA that Robin can speak about called Tech Watch, where innovators can come in at any time and talk to us and propose those ideas, and we've been able to support a whole number of those. BARDA has, frankly, been the catalyst for a number of those new technologies that we're seeing play out right in front of us with Ebola, in terms of new ways to make monoclonal antibodies, and flu, in terms of new ways to make vaccines that we just saw in H7N9.

Senator WHITEHOUSE. Let me get a few other answers, if I may, before my time expires, and I gather there'll be a firm gavel.

Dr. Robinson.

Ms. ROBINSON. As we're going forward, we're actually looking at influenza at what we call the holy grail, working with NIH and our partners at CDC and FDA to actually have universal influenza vaccines. We're also looking at immunotherapeutics, these monoclonal antibodies that may work against multiple strains of influenza and they're not vulnerable to emergent drug resistance.

With our other drugs, for biothreats and radiation illnesses, we are looking at stem cell therapies that one would have never even thought about. We're looking also at pre-symptomatic diagnostics going forward, so that before you present with a disease, we actually have a way of looking at people and knowing what direction they're going to go into and if they're actually going to be in harm's way for that particular disease. Again, we are at the cutting edge of innovation.

Senator WHITEHOUSE. Dr. Redd, 1 minute remaining.

Dr. REDD. Let me pass to Dr. Borio, then.

Dr. BORIO. We love innovation in products as well as how we approach the assessment of those products. Just to give you an example, a couple of weeks ago, we hosted a colleague from DARPA who came to socialize and began to engage with the FDA scientists on ideas that were very innovative and unprecedented. We are always looking forward to ways to engage and to be able to support development of those products.

Senator WHITEHOUSE. In my last 30 seconds, on the question of there being a different illness response at high weaponized doses that may require a different countermeasure, is that factual?

Dr. REDD. I think that may be something that's particular to each of the pathogens and exactly the way that it has been weaponized. For example, if anthrax spores are made smaller, they float around longer and, therefore, are easier to acquire. I think it might be something that would be somewhat true, in general, but there would be specific issues with each of the possible pathogens.

Senator BURR. I thank Senator Whitehouse. Senator Whitehouse has a deep interest in this, and we're working to gather a number of initiatives, and we'll have further hearings on some of those.

Robin, I did want to allow you 2 minutes, just if you want to highlight anything for the record that you would point to and say, "Here's a success at BARDA that absolutely is the top of the flagpole for us."

Ms. ROBINSON. I think that having actually 12 new products in the strategic national stockpile under Project BioShield, when many people 5 or 6 years ago didn't think that we would ever have more than three—I think that's extraordinary, and it's not just for anthrax and smallpox, but against a number of different threats and chemical and radiation illnesses. I think that's one.

On my pandemic influenza side, we have created an infrastructure in the United States that can provide a vaccine for everyone that wants one and during a pandemic, unlike we were able to do in 2009. We're able to do that now. I think this is a major achievement and, certainly, the American people can feel more secure about that. Again, as Dr. Lurie said, we make those faster and in greater quantities and, hopefully, as we go forward, even much better, not only in a pandemic, but also for seasonal influenza.

I think we've now shown with emergent infectious diseases that we can rapidly prepare and rapidly respond, and actually doing things much earlier in the pipeline than we normally would, and that we're capable of doing that and taking that transition even earlier if need be. We look forward to, I think, a very bright future, but we still have a long way to go.

Senator BURR. Great. Thank you for that.

I just want to, for the record, say the hearing record will remain open for 10 days so members can submit additional information for the record, additional questions, within that time if they'd like to.

Again, I thank all of our witnesses for being here. This was educational and enlightening, and if there's a takeaway for each one of you, it's that the committee is interested in this, and we will continue to watch in hopes that we continue to perfect the process even better.

Thank you.  
The hearing is adjourned.  
[Additional Material follows.]

## ADDITIONAL MATERIAL

RESPONSE BY NICOLE LURIE, M.D., MSPH TO QUESTIONS OF SENATOR ALEXANDER,  
SENATOR BURR, SENATOR ISAKSON, SENATOR KIRK, SENATOR SCOTT, SENATOR  
ROBERTS, SENATOR MURRAY, SENATOR MIKULSKI, SENATOR CASEY, SENATOR  
FRANKEN, SENATOR BALDWIN AND SENATOR WARREN

SENATOR ALEXANDER

*Question 1.* We thought the United States was prepared for threats like Ebola, but this fall showed us that we actually were not as ready as we should be. Issues like how to handle infectious waste and the type of health units capable of caring for and treating patients with Ebola showed vulnerabilities in our public health system.

Has this prompted a review of the extent to which our preparedness plans, scenarios, and drills truly do account for all-hazards, as is called for by the Pandemic and All-Hazards Preparedness Reauthorization Act? What has been the process for making sure we are prepared for these types of emergencies?

Answer 1. As required by Presidential Policy Directive 8 (PPD-8), the Department of Health and Human Services (HHS) participated in the development of the National Preparedness Goal and National Preparedness System. The National Preparedness Goal, released in September 2011, defines what it means for the whole community—from individuals, schools, businesses, and all levels of government—to be prepared for disasters and emergencies. Specifically, the National Preparedness Goal is defined as,

“A secure and resilient Nation with the capabilities required across the whole community to prevent, protect against, mitigate, respond to, and recover from the threats and hazards that pose the greatest risk.”

In order to realize this goal, the National Preparedness System has established an organized, systematic process for the whole community to move forward in preparedness activities. All Federal partners are utilizing the National Preparedness System to ensure that the Nation is prepared for all emergencies and disasters. The National Preparedness System ensures planning and preparedness initiatives to: identify and assess risk at multiple levels; estimate the capabilities needed to address such risks; build or sustain the required levels of capability; develop and implement plans to deliver those capabilities; validate and monitor progress; and review and update efforts to promote continuous improvement.

Specific to all-hazards planning, development of an HHS all-hazards plan started after the release of PPD-8 in September 2011. This plan includes general assumptions for all types of emergencies and disasters and ensures the Nation is prepared for all threats. The development of the HHS all-hazards plan was done in conjunction with the development of the National Response Framework and the Federal Interagency Operational Plans to make sure the concepts did not conflict with each other and to facilitate changes as planning documents were finalized. The HHS all-hazards plan and functional appendices were completed in April 2014.

HHS is also engaged in a number of other planning efforts to further preparedness and response to public health and medical threats. A number of efforts related to planning for both natural and international infectious disease outbreaks have been completed or are in progress. Specific efforts by HHS include:

- A joint HHS and Federal Emergency Management Agency (FEMA) interagency coordination plan for H7N9/MERS-CoV called the Interagency Pandemic Operations Plan (PanCap). This plan was completed in November 2013.
- Development of a Unified Coordination Group Plan to address the surge in unaccompanied children. This included a medical annex to address infectious disease detection, screening, and monitoring.
- A Biological Incident Annex to help planning for the Response and Recovery Federal Interagency Operational Plans, an effort HHS co-led with FEMA. The BIA will serve as a support document for the Pandemic Crisis Action Plan and the Federal Medical Countermeasures Plan, as well as existing regional, State, and local plans. A final review is expected by the end of August 2015 with a target completion date of the end of September 2015.
- In collaboration with FEMA, the development of Federal medical countermeasures (MCM) support plans for the Urban Area Security Initiative. These plans enhance existing mass MCM dispensing plans and support responses to naturally occurring pandemics and deliberate biological outbreaks in these high-threat, high-density Urban Areas.

- The Department of Defense Operation Vigilant Sentry appendix which describes how ASPR collaborates with DHS to conduct medical screening, triage, provide medical treatment, and implement public health measures necessary to prevent the introduction or spread of communicable diseases into the United States.

Related to Ebola planning:

- HHS, in collaboration with its Federal Emergency Support Function partners, is developing the U.S. Government Ebola Virus Disease Plan. The purpose of the plan is to describe the integrated concept of operations, processes, and organizational constructs that the U.S. Government will utilize to prevent, protect against, mitigate, respond to, and recover from EVD. The plan will guide the U.S. Government in preparing to manage and contain Ebola domestically in support of State, local, tribal and territorial governments, and internationally in support of partner nations. It also will clarify the roles and responsibilities of Federal interagency partners and other supporting entities to establish clear lines of responsibility and eliminate duplication of effort. This plan is scheduled to be completed in fall 2015.

- Participation in the interagency Latin America/Caribbean EVD planning process to help foreign partners deter mass migration, assist the Department of Homeland Security (DHS) Customs and Border Protection in determining medical screening/processing support, and assist the United States Coast Guard in determining maritime medical screening and treatment guidance for para-professional medical providers.

- HHS Support Plan for the First Case of Ebola Diagnosed in the United States in August 2014.

*Question 2.* After the failure to correctly diagnose Mr. Thomas Duncan on his first visit to the emergency department in Texas, several areas were identified for improvement to ensure that hospitals around the Nation are prepared to recognize a potential case of Ebola, isolate the individual, and provide a timely diagnosis. A key component is awareness among health professionals about the importance of a travel history to an Ebola epidemic country.

Please identify actions you took to improve awareness among health professionals, including working with associations and professional organizations.

*Answer 2.* An important lesson learned in the U.S. response to Ebola was that the safety of health care workers, from clinicians and laboratory workers to ancillary staff, must be a foremost responsibility during health care system preparedness and response activities. Health care worker safety is best achieved through the implementation of infection control, appropriate use of personal protective equipment (PPE), continuous training, demonstration of competencies, and participation in frequent exercises. Moreover, we must ensure that Ebola patients are safely and well cared for in the U.S. health care system and that frontline health care workers are trained to recognize and isolate a person with suspected Ebola. These are the cornerstones of the Hospital Preparedness Program (HPP) Ebola funding opportunity announcement (FOA): EP-U3R-15-002: *HPP Ebola Preparedness and Response Activities*.

On April 15, 2014, the Office of the Assistant Secretary for Preparedness and Response's (ASPR's) HPP program circulated frequently asked questions concerning Ebola. These questions were developed by physicians associated with HPP-supported health care coalitions and U.S. health care professionals to improve outreach and awareness about the Ebola virus. During the summer of 2014, in collaboration with the Centers for Disease Control and Prevention (CDC), ASPR began developing and disseminating checklists to prepare health care providers for Ebola. These checklists provide practical and specific suggestions to make sure health care workers, facilities, and health care coalitions are able to detect possible Ebola cases, and that employers are able to protect their employees, and respond appropriately. These checklists are updated regularly and are available on both ASPR's and CDC's Web sites.

Further, beginning in August 2014, ASPR coordinated, participated in, and contributed to numerous webinars, conference calls, and trainings with public health and health care professionals, associations, professional organizations, and health care facility leaders. Participating external stakeholder groups include State and local public health departments, the Association of State and Territorial Health Officials, the American Hospital Association, the Association of American Medical Colleges, nursing professional organizations, emergency medical service providers, and health care coalitions. These direct outreach efforts reached over 160,000 individuals in the health care and public health fields.

ASPR has also promoted the use of National Standards for Culturally and Linguistically Appropriate Services (CLAS Standards) in Health and Health Care and in education to ensure language access and to avoid stigma.<sup>1</sup>

*Question 3.* How are you working with hospitals in the Hospital Preparedness Program to review surge capacity for all-hazards? What are the specific goals for setting up Ebola Treatment Centers and how does this fit within an all-hazards framework?

*Answer 3.* In order to prepare the U.S. health care system to respond to events in a coordinated and collaborative manner, rather than facility-by-facility, ASPR has been providing resources to 62 State, territory, and local awardees through HPP. In 2012, HPP transitioned from facility-based capacity building to coalition-based capability development. This includes eight health care preparedness capabilities: (1) healthcare system preparedness; (2) healthcare system recovery; (3) emergency operations coordination; (4) fatality management, (5) information sharing; (6) medical surge; (7) responder safety and health; and (8) volunteer management. The medical-surge capability is the ability to provide adequate medical evaluation and care during incidents that exceed the limits of the normal medical infrastructure within the community. This includes the ability of health care organizations to survive an all-hazards incident and maintain or rapidly recover operations that were compromised.

HPP awardees must maintain all-hazards public health emergency preparedness and response plans as part of their cooperative agreement. Awardee performance in regards to health care preparedness is evaluated annually through annual program evaluations, progress reporting, and site visits. Further, HPP awardees must ensure that hospitals have all-hazards and hazard-specific preparedness and response plans, as well as the space, staff, and supplies needed to provide immediate bed availability. This is necessary to assure appropriate early medical care for individuals affected by disasters and public health incidents.

To assist hospitals in their medical surge efforts, HPP released a new hospital surge evaluation tool in December 2014 that was designed to identify gaps in a hospital's preparedness and help assess its ability to respond to a mass casualty event. The tool takes the form of a no-notice drill and incorporates real-life health care considerations in acute care settings. The tool is intended for use by hospital emergency managers, hospital administrators, and clinical staff to assess and improve their hospital's surge plans. Hospitals need to exercise their preparedness for a mass casualty incident regularly. This tool can help hospital emergency managers make recurring tabletop exercises a reality by providing a fully developed tabletop exercise that can be used at their facilities. In some respects, this tool can be thought of as "Surge Evaluation in a Box." HPP also is developing a companion surge evaluation tool for health care coalitions.

A total of \$194.5 million was awarded through the HPP Ebola FOA (EP-U3R-15-002: *HPP Ebola Preparedness and Response Activities*) to ensure our Nation's health care system is ready to safely and successfully identify, isolate, assess, transport, and treat patients with or under investigation for Ebola. While the primary focus is on preparedness for Ebola, as required by Title VI of Division G of the Consolidated and Continuing Appropriations Act, 2015, it is likely that preparedness for other novel, highly pathogenic diseases will also be enhanced through these activities.

In December 2014, HHS released its *Interim Guidance for U.S. Hospital Preparedness for Patients under Investigation or with Confirmed Ebola Virus Disease: A Framework for a Tiered Approach*, which outlines the different roles U.S. acute health care facilities can assume in preparing to identify, isolate, and evaluate or treat patients with possible or confirmed Ebola. These responsibilities include serving as Ebola treatment centers, assessment hospitals, and frontline health care facilities. In addition to outlining the roles these facilities can assume, the guidance provides minimum standards each facility must meet in order to help State health officials assess facilities and assist with the designation process. Building upon the tiered State and jurisdiction based hospital approach and meeting Congress' regional directive, HHS provided a portion of the total HPP Ebola resources to establish a nationwide, regional treatment network for Ebola and other infectious diseases. This regional treatment network balances geographic need with differences in health care institutional capabilities and accounts for the potential risk of needing to care for an Ebola patient. This overall Ebola health care treatment and assessment network currently consists of:

<sup>1</sup> See <https://www.thinkculturalhealth.hhs.gov/content/clas.asp> and <https://www.thinkculturalhealth.hhs.gov/Content/ContinuingEd.asp>.

- Nine regional Ebola and other special pathogen treatment centers that can be ready within a few hours to receive a confirmed Ebola patient from their region, across the United States, or medically evacuated from outside of the United States, as necessary. These hospitals will also have enhanced capacity to care for other highly infectious diseases.

- State or jurisdiction Ebola treatment centers (61 as of July 21, 2015) that can safely care for patients with Ebola in the event of a cluster of Ebola patients that overwhelm a regional Ebola and other special pathogen treatment center. Clinical judgment, available logistical resources, and patient preference may indicate the patient should receive treatment at a state/jurisdiction Ebola treatment center rather than be transferred to a regional Ebola and other special pathogen treatment center.

- Assessment hospitals that can safely receive and isolate a person under investigation for Ebola and care for the person until an Ebola diagnosis can be confirmed or ruled out, and until a discharge or transfer has been completed.

- Frontline health care facilities that can rapidly identify and triage patients with relevant exposure history and have symptoms compatible with Ebola. These facilities would then coordinate patient transfer to an Ebola assessment hospital.

With funding provided in the HPP Ebola FOA, all HPP awardees will develop and implement a health care system concept of operations (CONOPS) for care of Ebola patients. This CONOPS must link State activities related to the active monitoring of returning travelers to designated assessment or treatment hospitals. From there, they would ensure patients can be safely transported to a regional Ebola or special pathogen treatment center and/or a State or jurisdiction Ebola treatment center. Each awardee's health care system CONOPS for Ebola will be maintained and exercised annually throughout the 5-year project period.

Further, HPP Ebola FOA awardees will assure readiness of regional Ebola and special pathogen treatment centers, State- and jurisdiction-based Ebola treatment centers, assessment hospitals, and health care coalitions (with, at a minimum, front-line health care facilities and EMS) through quarterly or annual trainings and exercises, depending on their respective roles. Exercises in the first year should be specific to Ebola. If in subsequent years there are no global outbreaks of Ebola, exercises may address other infectious diseases, such as MERS-CoV and measles. The PPE trainings that health care facilities around the Nation have been conducting for Ebola, such as training covering donning and doffing of PPE, have relevance to other and more common infections. While the PPE (*e.g.*, Tyvek suits) might be different for other infectious diseases, the actual process for removing the PPE, such as gloves, without contaminating oneself is the same and will assist with health care acquired infections and other pathogens.

SENATOR BURR

*Question 1.* PAHPRA set forth a new requirement for the ASPR to brief the President's National Security Advisor on a periodic basis. Since being confirmed to serve as the ASPR, how many times have you briefed the National Security Advisor?

Answer 1. The Assistant Secretary for Preparedness and Response (ASPR) annually updates the National Security Advisor, and the National Security Staff on the status of the Strategic National Stockpile (SNS). This is a report that is required both by statute<sup>2</sup> and by Homeland Security Presidential Directive (HSPD-21), which directs the HHS Secretary, through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), to comprehensively examine the SNS for- mularly each year to ensure the most effective use of the limited resources available to stockpile those critical medical countermeasures that will be required in an emergency. The recommendations, developed by subject matter experts and senior policy leaders, inform resource management and procurement policy for the most appropriate set of medical countermeasures to acquire and maintain in the SNS.

Furthermore, ASPR represents the HHS Office of the Secretary on a variety of National Security Council Interagency Policy Committees, which serve to inform the National Security Advisor and staff regarding policy and technical issues related to naturally occurring as well as deliberate public-health emergencies on a regular basis. The ASPR meets regularly to update the Deputy National Security Advisor on any new or potential event(s) that may present a risk to the health security, including Middle East Respiratory Syndrome (MERS-CoV) and avian influenza A (H7N9).

<sup>2</sup> 42 U.S.C. 247d-6b(a).

*Question 2a.* The ASPR is responsible for the hospital preparedness program and our Nation's medical surge capacity. We have a handful of special treatment units and beds that we have used to provide treatment to Ebola patients in the United States. The experiences that these facilities gained in providing care to these patients underscored the significant challenges in providing treatment to patients with Ebola and similar conditions, including the high volume of medical waste they produced.

Is ASPR reexamining any facets of our medical surge capacity based on our experiences with Ebola treatment?

*Answer 2a.* A few important lessons learned in the recent response to Ebola include: health care worker safety from clinicians and laboratory workers to ancillary staff, recognizing that care for Ebola patients is clinically complex and demanding, and understanding that early case recognition is critical for preventing spread and improving outcomes. These lessons highlight the importance of adequate and sustained preparedness funding and the need for a national network of hospitals for treating highly pathogenic infectious diseases.

The Hospital Preparedness Program's (HPP) preparedness and response strategy is concerned with making sure HPP awardees can meet eight national health care preparedness capabilities. These capabilities provide flexibility and address all-hazards, including: (1) health care system preparedness, (2) health care system recovery, (3) emergency operations coordination, (4) fatality management, (5) information sharing, (6) medical surge, (7) responder safety and health, and (8) volunteer management. Health care system preparedness, emergency operations coordination, and health care system recovery address the planning and preparation required to support efforts in all stages of an incident (preparedness, response, recovery, and mitigation). Fatality management and medical surge capabilities focus on rapid health care coordination, the ability to scale up operations, and resource allocation during an emergency. Information sharing highlights the need for the health care system to share information during an emergency with both system members and the public. Responder safety and health identifies and procures resources needed to protect health care workers. Volunteer management is the ability to coordinate and utilize volunteers to augment incident operations.

Research and history demonstrate that if HPP awardees strengthen their local health care preparedness capabilities, they will be ready to respond to any given disaster or public health event. It is vital that health care systems maintain a baseline level of preparedness on all capabilities, so that for whatever the event (Ebola, terrorist attack, or natural disaster) local systems can respond quickly and effectively to save lives.

HPP awardees originally targeted all eight health care preparedness capabilities when the program transitioned to a health care coalition-based approach in 2012. As a result of funding reductions in 2014, many awardees have had to prioritize their efforts by targeting five of the eight capabilities. An HPP impact assessment of this reduction showed that 68 percent of awardees were not able to sustain progress made since 2012 on responder safety and health. Furthermore, 90 percent of awardees reduced exercises, evaluations, and corrective actions. Seventy percent reduced health care worker education and training. Responder safety and health was not among the five prioritized capabilities for many awardees and problems with health care worker safety during the Ebola outbreak underscored the need to re-emphasize responder safety.

To re-emphasize responder safety and health, funding from both the Ebola emergency supplemental and the annual cooperative agreement program will support activities to enhance this capability including exercises, health care worker trainings, and optimizing the planning and management of PPE for health care workers.

Additionally, strong regional coordination through health care coalitions (HCCs) can mitigate challenges associated with scarce supplies and resources during an outbreak or other public health event. For example, if a regional health care system has extra PPE available in some of its facilities, this equipment can be dispersed to local health care providers in need. The need for a national network of hospitals that are capable of treating highly pathogenic infectious diseases is addressed through the HPP Ebola funding awarded in May and June 2015. The capabilities and capacity of HPP awardees, and the health facilities and HCCs they will support through the supplemental Ebola funding, will be maintained for the full 5-year project period through quarterly or annual exercises and trainings, according to their respective roles. While the focus is on preparedness for Ebola, as required under Title VI of Division G of the Consolidated and Continuing Appropriations Act, 2015, it is likely that preparedness for other novel, highly pathogenic diseases will also be enhanced through these activities.



*Question 2b.* How is ASPR ensuring that our projected medical surge capacity is sufficient for the threats we may face?

Answer 2b. HPP awardees must maintain all-hazards health care system emergency preparedness and response plans to meet requirements within the HPP cooperative agreement. Awardee performance on the health care preparedness capabilities is evaluated annually through program evaluations, progress reporting, and site visits. Further, HPP awardees must make sure hospitals have all-hazards and hazard-specific preparedness and response plans, as well as the space, staff, and supplies needed to provide immediate bed availability and assure appropriate early medical care for individuals affected by disasters and public health incidents.

HPP annually collects planning information from awardees on eight health care preparedness capabilities. Information sharing and medical surge were ranked as the most important capabilities by HPP awardees in each budget year 2012–15. Additionally, medical surge and health care system preparedness, which includes health care coalition development, were the most highly prioritized capabilities in awardees' funding allocations in 2012–15.

To assist hospitals in their medical surge efforts, HPP released a new Hospital Surge Evaluation Tool in December 2014 that was designed to identify gaps in a hospital's preparedness and help assess its ability to respond to a mass casualty event. The tool takes the form of a no-notice drill and incorporates real-life considerations in acute care settings. The tool is intended for use by hospital emergency managers, hospital administrators, and clinical staff to assess and improve their hospital's surge plans. Hospitals need to exercise their preparedness for a mass casualty incident regularly. This tool can help hospital emergency managers to make recurring tabletop exercises a reality by providing a fully developed tabletop exercise that can be used at their facilities. In some respects, this tool can be thought of as "Surge Evaluation in a Box."

*Question 2c.* How is ASPR ensuring that the lessons we learn from our experiences with Ebola are being taken into consideration and reflected in our preparedness and response strategies? For example, how do we ensure that the medical waste issues are not an issue in future response efforts?

Answer 2c. While most of the Ebola outbreak has occurred in West Africa, HHS and other critical public health preparedness stakeholders have been working to strengthen domestic preparedness, should this or another infectious disease become an epidemic domestically. Many components of HHS have partnered together to support the response in West Africa and strengthen domestic preparedness. Partners include: the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and operational divisions within the HHS Office of the Secretary such as the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Office of the Assistant Secretary for Health, and the Office of Global Affairs.

Representatives of these components recently met to discuss an after action review and report process to identify successes and identify any gaps in planning and response efforts. As this effort moves forward, HHS will gather information, draft an after-action document, and develop an improvement plan to strengthen preparedness and response to not only Ebola but other potential infectious disease outbreaks that have the potential to impact public health.

A few important lessons learned throughout the national health care system in response to Ebola include health care worker safety from clinicians and laboratory workers to ancillary staff, recognizing that care of Ebola patients is clinically complex and demanding, and understanding that early case recognition is critical for preventing spread and improving outcomes. These lessons highlight the importance of adequate and sustained preparedness funding and the need for a national network of hospitals for treating highly pathogenic infectious diseases.

HHS, in partnership with Federal and State partners, has made significant advances in the safe removal and transport of medical waste during the Ebola response, all of which can be applied in a future event. ASPR, working closely with CDC and the Department of Transportation, developed a mechanism that allowed for the safe removal and legal transport of contaminated medical waste from civilian health care facilities treating confirmed cases of Ebola. This led to the Pipeline and Hazardous Materials Safety Administration issuing a nonsite specific special permit (Special Permit DOT-SP 16279) to certain waste haulers, which authorizes the transportation and disposal of waste contaminated with or suspected of being contaminated with Ebola.

As part of the HPP Ebola FOA (EP-U3R-15-002: HPP Ebola Preparedness and Response Activities), awardees are directed to take a number of steps that address

infectious waste for the full 5 years of the Ebola cooperative agreement project period. These include:

- Assuring the readiness of all nine regional Ebola and other special pathogen treatment centers, the 61 State or jurisdiction Ebola treatment centers and assessment hospitals across the country by making sure their capability to handle Ebola-contaminated or other highly contaminated infectious waste. This can be done through contract with a waste management facility within the State or jurisdiction willing and able to incinerate and dispose of Ebola waste or by purchasing an on-site, high-volume autoclave capable of sterilizing hospital waste used in the care of a patient with Ebola. This can also be done by having a written agreement with another State willing to assume these responsibilities.
- Ensuring that EMS and interfacility transport systems are included in Ebola coalition planning. This includes making sure medical waste generated through the care of Ebola patients for EMS is safely managed through their own plans, a hospital's plan, or a separate coalition plan.

While focus remains on preparedness for Ebola as required under Title VI of Division G of the Consolidated and Continuing Appropriations Act, 2015, it is likely that preparedness for other novel, highly pathogenic diseases will also be enhanced through these activities.

Further, the National Ebola Training and Education Center (NETEC), which was awarded funding in July 2015 through a separate FOA (EP-U3R-15-003) will offer expertise, training, technical assistance, peer review, monitoring, and recognition to State health departments, regional Ebola and other special pathogen treatment centers, State and jurisdiction based Ebola treatment centers, and assessment hospitals. The NETEC is a consortium of all three U.S. hospitals that successfully and safely treated patients with Ebola: Emory University in Atlanta, GA; University of Nebraska Medical Center/Nebraska Medicine in Omaha, NE; and Bellevue Hospital Center in New York, NY. One of the activities required of the NETEC is to create and maintain a comprehensive suite of timely and relevant educational materials (*e.g.*, curricula, training, templates, train-the-trainer modules, tools, simulations, online resources, webinars) for policies and procedures related to the care of patients with possible Ebola and other special pathogens. Resources must align with government guidance and evolving scientific and clinical evidence bases. One topic they will address is handling Ebola-contaminated or other highly contaminated infectious waste.

*Question 3.* How is the ASPR ensuring that the drills and exercises the ASPR is leading are training to the most appropriate protocols and across various threat scenarios so our Nation is better prepared for the full range of threats we may face?

*Answer 3.* The Secretary of Homeland Security conducted a strategic national risk assessment to help identify types of incidents that pose the greatest threat to the Nation's homeland security. Representatives from Federal interagency offices have supported this effort and released the Strategic National Risk Assessment (SNRA) in December 2011. The SNRA describes a wide range of threats and hazards that warrant national attention—threats include animal disease outbreaks, earthquakes, floods, pandemic outbreaks, chemical spills, dam failures, aircraft as a weapon, biological terrorists attacks, and explosive terrorist attacks, to name a few.

ASPR's drills and exercises are based on the threats and hazards identified in the SNRA. ASPR also bases current drills and exercises on the findings contained within the Department of Homeland Security's National Preparedness Report. The National Preparedness Report is published annually and summarizes progress in building, sustaining, and delivering the core capabilities outlined in the National Preparedness Goal.

In order to ensure response teams are adequately prepared and trained, the National Disaster Medical System (NDMS) utilizes the NDMS Fundamentals 100 series course designed and administered in collaboration with the Department of Homeland Security's Center for Domestic Preparedness in Anniston, AL. This week-long course provides didactic and hands-on, full-context training for response to a mass casualty situation. Specifically, the course targets training in: National Incident Management System (NIMS) command, control, and coordination structures; health and safety hazard assessments; dissemination of guidance and resources to support environmental health and safety actions for response personnel; recognition of cache equipment; and the capability of NDMS teams to provide medical care to patients with access and/or functional needs. Current programmatic resources enable approximately 20 percent of the NDMS workforce to attend the Fundamentals courses annually.

*Question 4a.* Emergency Support Function #8 sets forth the coordination of medical and public health services as part of the National Response Framework, which was updated in May 2013. The previous document ESF #8 clearly set forth that the Secretary of Health and Human Services leads all Federal public health and medical response to public health emergencies and incidents covered by the National Response Framework and that the ASPR coordinates national ESF #8 preparedness, response, and recovery actions, which is also set forth by PAHPA.

Was the office of the ASPR involved in updating this document? If not, why considering the subject matter at hand?

Answer 4a. ASPR's Office of Emergency Management (OEM) was involved in updating this document. OEM led a workgroup comprised of HHS divisions to review and update the annex.

*Question 4b.* Why did this updated document remove the reference to the ASPR?

Answer 4b. Ultimately, the content of all of the ESF Annexes to the National Response Framework (NRF) were updated to reflect the direction contained within the Presidential Policy Directive 8 (PPD-8) Implementation Plan that:

1. The Planning Frameworks are intended to provide succinct descriptions, at a high level, of the steps taken to prepare to deliver the necessary capabilities, and;
2. The Planning Frameworks are not intended to be traditional operations plans, concept of operations plans or detailed plans for action.

Under these guidelines and in the process of aligning to the second edition of the NRF, all internal departmental policies, responsibilities, and procedures were removed from ESF Annexes.

*Question 5.* Since 2006, limited PREP Act declarations have been issued for various threats. The current PREP Act declaration related to anthrax, smallpox, and other threats is set to expire on October 1, 2015. What steps are being taken to renew these declarations to ensure there is no gap in the PREP Act protections contained within the current declaration?

Answer 5. PREP Act declarations covering medical countermeasures against anthrax, smallpox, botulinum toxin, acute radiation syndrome, and pandemic influenza A viruses expire on December 31, 2015, the PREP Act declaration for certain vaccines against Ebola expires on December 3, 2015, and the PREP Act declaration for a therapeutic against Ebola expires on April 8, 2016. This summer, HHS, through the PHEMCE, has been reviewing options and will develop recommendations for the Secretary regarding extension of PREP Act coverage under these declarations past 2015.

*Question 6.* How is the 5-year medical countermeasure plan that was recently submitted to Congress being shared with outside stakeholders?

Answer 6. ASPR's Biomedical and Advanced Research Development Authority (BARDA) has provided briefings on the PHEMCE multiyear budget on several occasions across various forums. BARDA Director Dr. Robin Robinson has presented to biodefense organizations (e.g., Alliance for Biosecurity), to industry conventions (e.g., BIO), at BARDA Industry Day, at international biodefense meetings (e.g., chemical, biological, radiological, nuclear, and explosives conferences), at congressional staff briefings, and during other formal and informal speaking engagements.

SENATOR ISAKSON

*Question 1.* Secretary Lurie, I was pleased to see that ASPR released its FOA last Friday regarding the emergency funding allocated in the CROmnibus. The FOA released \$194 million to be channeled through the State departments of public health for hospital preparedness.

This is less than half of the money that Congress provided for this purpose. I hope that ASPR has plans to spend more of the remaining funding, which I understand to be about \$375 million, directly to our hospitals that are on the front line.

Can you please outline your plan for this remaining funding that Congress directed to hospital preparedness?

Answer 1. The Hospital Preparedness Program (HPP) is awarding \$201.5 million of the total funding appropriated to the Department of Health and Human Services under Title VI of Division G of the Consolidated and Continuing Appropriations Act of 2015. This includes:

- \$194.5 million through the *HPP Ebola Preparedness and Response Activities* funding opportunity announcement (FOA), and
- \$7 million (together with \$5 million from CDC for a total of \$12 million) for the National Ebola Training and Education Center (NETEC) FOA.

The remaining funding is not allocated to specific activities either in the statute or in report language. The language allows resources to be used for Countermeasure Injury Compensation Program expenses, reimbursement of domestic transportation and treatment costs for individuals treated in the United States for Ebola, Ebola patient treatment cost reimbursement, and other preparedness and response needs. The statute also provides transfer authority of funds appropriated under title VI to specific Departmental components to meet critical needs that may arise rapidly. For example, resources could be used to scale-up Ebola response efforts in Guinea, Sierra Leone, and neighboring countries if the outbreak spreads or if the caseload dramatically increases. As HHS continues its work to develop an Ebola vaccine, these resources could also be used to scale-up production and support initial activities for a potential vaccination campaign.

SENATOR KIRK

*Question 1.* Guidance from the National Strategy on Pandemic Influenza recommends maintaining enough antivirals to treat 25 percent of the U.S. population. Do you have plans to replace existing product in the Strategic National Stockpile based on changes to its patent exclusivity? Do you have plans to replenish existing stock that will soon expire to maintain preparedness? How are you engaging the private sector to address both issues?

Answer 1. By 2007, the Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response (ASPR) met the domestic influenza antiviral drug stockpile goals established in the National Strategy for Pandemic Influenza (2005). Today, the Centers for Disease Control and Prevention's (CDC) Strategic National Stockpile (SNS) maintains an influenza antiviral drug stockpile that continues to address this function in preparation for a potential influenza pandemic.

During 2009, the United States distributed more than 11 million treatment courses of influenza antiviral drugs to the States, replenished those products accordingly, and subsequently replenished stockpiled products that had expired. In addition, the shelf life of these products has been extended by the Food and Drug Administration (FDA) in light of data from applicants supporting stability and demonstrating longer shelf life (e.g., 5 to 10 year expiry dating for Tamiflu). During annual reviews of the SNS formulary, as required by the Pandemic and All-Hazards Preparedness Act (PAHPA), the inventory of influenza antiviral drugs are assessed and adjusted as needed based on strategic goals, product composition, expiring product, and general population needs. SNS acts on these recommendations by acquiring additional influenza antiviral drugs. CDC and BARDA have met with companies that may have generic versions of influenza neuraminidase inhibitor products and will consider them in replenishment procurement plans if/when generics are approved by the FDA in coming years.

SENATOR SCOTT

*Question 1.* In December, it was announced that after less than 3 months on the job Ebola Czar Ron Klain would be leaving his post and returning to the private sector. When Klain was first appointed to this position I know everyone had serious questions as to whether the Administration had picked the right man for the job, given the fact he had zero public health experience. Dr. Lurie, given that you are the Assistant Secretary for Preparedness and Response, and have the credentials necessary for responding to an Ebola or any public health crisis, did you have any input into this decision? Will you have a roll in future appointments, should another public health crisis arise?

Answer 1. The Secretary of the Department of Health and Human Services (HHS) convened daily (or more) meetings with a diverse team of senior department leadership officials that included, but was not limited to: the Assistant Secretary for Preparedness and Response (ASPR), the Assistant Secretary for Health, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA). This was done to make sure the Department did everything possible to respond to Ebola both domestically and in West Africa.

ASPR, as the principle advisor to the HHS Secretary, regularly met with Ron Klain and continues to meet regularly with senior government officials to support the government's comprehensive response to Ebola. ASPR's operating divisions continue to provide leadership, expertise, and support for the implementation of numerous preparedness, response, and recovery activities. For example, throughout the Ebola response, ASPR has led and supported the development of medical countermeasures and policies pertaining to use and clinical trials; the development of

standards of care for Ebola patients and clinical guidance; the advancement of domestic health care system preparedness; interagency coordination for patient movement issues and repatriation; and interagency and international coordination to support response efforts in West Africa and to discuss and harmonize domestic response policies with allied countries. ASPR also led a series of focused domestic preparedness and response readiness, modeling, and science and budget activities.

As you know, ASPR serves at the request and privilege of the President of the United States and under the leadership of the Secretary of HHS. Ebola required a multifaceted Government response and the President chose Mr. Klain to coordinate this effort. Mr. Klain led a successful response and has transitioned to a new endeavor. ASPR is a leader in preparing our Nation and its communities to respond to and recover from public health and medical disasters and emergencies. With that in mind, ASPR stands ready to lead our Nation during the next public health crisis and will remain available to the President and to the Secretary for any advice and guidance they request.

*Question 2.* During the height of the Ebola outbreak, I'm proud to say that South Carolina hospitals stepped up to the challenge and quickly created a statewide response system that included Greenville Health System, Spartanburg Regional Healthcare System, Palmetto Health, and the Medical University of South Carolina. Our hospitals and their staff went above and beyond to prepare, and remain prepared, for a worst case scenario. Though the CDC has not officially designated any hospital in South Carolina an official "Ebola Treatment Center," I'm confident our hospitals would be able to deliver the highest quality of care should any public health crisis arise. However, I am concerned about preparedness in the rural areas in our State, where providers have fewer resources to prepare and local coordination is often more difficult.

What is being done to assist these rural areas in their response readiness? Related to this is the overall cost issues that arise during a sudden public health crises. What is being done to ensure appropriate reimbursement for large and rural hospitals, not only for rapid stepped up preparation but also for the expensive treatment of patients?

*Answer 2.* The Hospital Preparedness Program (HPP) awarded \$162 million in May 2015 through funds made available through the Ebola supplemental appropriation. This funding was distributed via formula to all 62 HPP awardees. This includes the 50 States, DC, select metropolitan jurisdictions (Chicago, Los Angeles County, and New York City), U.S. territories, and freely associated States to support health care facilities that are capable of serving as Ebola treatment centers and assessment hospitals for their States or jurisdictions. The funding will also support health care coalitions (HCCs) to prepare frontline hospitals (including those in rural areas), emergency medical services agencies, and the overall health care system. The funding formula for the HPP Ebola awards took into account Ebola risk, based on the travel patterns of individuals coming from the affected countries. It also reflected West African diaspora population centers and jurisdictions with enhanced airport entrance screenings. This was done to make sure those States and localities most likely to have a case of Ebola are fully prepared.

For Part A of the HPP Ebola FOA (which includes the \$162 million described above), awardees must limit their direct costs (excluding sub-awards to HCCs and health care facilities) to no more than 10 percent of their allocation. Of the funds for sub-awards, at least 30 percent was allocated to health care coalitions in their jurisdiction and no more than 70 percent was used to provide funding directly to Ebola treatment centers and/or assessment hospitals.

One of the required Part A activities is for awardees to develop and implement a health care system concept of operations (CONOPS) for the care of Ebola patients. This CONOPS links State activities related to active and direct active monitoring of returning travelers to designated assessment hospitals and treatment hospitals, and ensures that patients can be safely transported to a regional Ebola and other special pathogen treatment center and/or a State or jurisdiction Ebola treatment center in the event that they are not the same or the regional facility cannot accept patients. Each awardee's health care system CONOPS for Ebola will be maintained and exercised annually throughout the project period.

The 30 percent set aside for HCCs is intended to develop the capabilities of HCCs and enable their members to care for Ebola patients. HCCs incentivize diverse and often competitive health care organizations with differing priorities and objectives to work together. HCCs collaborate to ensure that each member has the necessary medical equipment and supplies, real-time information, communication systems, and trained health care personnel to respond to an emergency. Nationwide, HCC membership is growing rapidly; between 2013 and 2014, there was a 47 percent in-

crease in membership and there are currently about 24,000 health care and public health partners participating, from local health departments to hospitals, EMS, and emergency management agencies. Strong regional coordination through HCCs can mitigate challenges associated with scarce supplies and resources during an outbreak or other public health event and help each patient receive the right care at the right place at the right time. For example, if a regional health care system has extra PPE available in some of its facilities, this equipment can be dispersed to local health care providers who need it.

As part of the HPP Ebola FOA, HCCs will:

- Ensure that all coalition partners have access to personnel protective equipment (PPE), trainings, and exercises according to their respective role in the health care system.
- Purchase PPE or support facility purchase and stockpile, preferably using vendor-managed inventories and mutual aid agreements at the coalition, community, or regional level.
- Rapidly distribute or re-distribute PPE to a facility within their coalition as needed. At a minimum, coalitions will coordinate with partners to obtain visibility of the PPE supplies available at health care facilities in their communities and ensure it can be moved rapidly as needed.
- Ensure the competency of health care workers to identify, assess, and treat suspected or confirmed patients with Ebola through annual training.
- Conduct annual coalition level exercises with, at a minimum, frontline facilities and EMS. Exercises in the first year should be specific to Ebola. If in subsequent years, there are no global outbreaks of Ebola, exercises may address other infectious diseases, such as MERS-CoV and measles.
- Conduct training and assist coalition partners in final preparations to assure State or jurisdiction Ebola treatment centers and assessment hospitals are able to accept a patient (in the event of a small cluster of cases) within 72 hours of accepting a confirmed patient from the region's Ebola or other special pathogen treatment center. This includes coordination with EMS and interfacility transport agencies.
- Ensure that EMS and interfacility transport systems and 911/Public Safety Answering Points are included in Ebola coalition planning.
- Provide funding, as necessary, to EMS agencies for Ebola preparedness activities, such as purchasing PPE, training on PPE and other Ebola-related protocols, and exercises.
- Ensure that medical waste generated from the care of Ebola patients by EMS is safely managed through their own plans, a hospital's plan, or a separate coalition plan.
- Integrate health care system preparedness and infection control through health care coalition engagement with State Healthcare-Associated Infection/Infection Control advisory groups, established with funding and guidance from CDC's Epidemiology and Laboratory Capacity for Infection Control program. This is also done to consider how a regional emergency preparedness structure could support improved infection control for coalition members.

Awardees can use their discretion to provide supplemental funds to sub-recipient health care facilities and coalitions for previous Ebola preparedness costs incurred since July 2014; however, awards may not be used to reimburse health care facilities for direct patient treatment costs. HPP seeks to build capabilities within the entire health care system to better prepare communities for future outbreaks of Ebola and other highly pathogenic diseases illnesses.

A separate process has been developed to reimburse health care facilities for uncompensated costs associated with the domestic treatment and transportation of confirmed patients with Ebola. Health care facilities began submitting claims on April 15, 2015.

SENATOR ROBERTS

*Question 1a.* According to many of your industry partners, the move in authority of BARDA contract's to ASPR's Office of Acquisitions Management, Contracts and Grants (AMCG) has caused unnecessary delays and uncertainty regarding the time sensitive review of BARDA's medical countermeasures (MCM) development contracts.

Do you think BARDA should be allowed to negotiate and award its own advanced R&D contracts as it has done in the past?

Answer 1a. The Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response (ASPR) always seeks the best approaches for preparing contracts, grants, cooperative agreements, and Other Transaction Agreements (OTAs) with industrial and

academic partners to support advanced development, manufacturing, testing, and purchase of medical countermeasure candidates and products for preparedness and response to the medical consequences of chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza, and emerging infectious diseases.

*Question 1b.* Would you be willing to examine the possibility of re-instating BARDA's contracting authority as a means to accelerate the development of critical MCM projects?

Answer 1b. ASPR and BARDA are constantly seeking ways to improve the efficiency and quality of the procurement process and we welcome any suggestions you have for improvement. Maintaining a separate contracting office benefits ASPR as a whole, including BARDA and other operating divisions. Thus far, it has been an effective process. From the 2009–10 H1N1 pandemic influenza response through the current Ebola outbreak, ASPR and BARDA has benefited from senior-level, experienced contracting officers executing timely contract actions.

*Question 2.* When Project BioShield was created, OMB independently reviewed all procurement contracts since the funds were derived from DHS but the program was administered by HHS.

Now that BioShield funds are also housed at HHS, would you support removing this additional step of OMB approval in an effort to streamline the process and reduce wait times for these MCM contracts?

Answer 2. ASPR and BARDA are always looking for ways to improve our efficiency and we welcome your suggestions. OMB provides valuable oversight and helps maintain our quality and the whole of Government approach to these important issues. Similarly, according to the Project BioShield Act of 2004, DHS continues to play an important role in reviewing and recommending use of these funds.

SENATOR MURRAY

*Question 1.* PAHPRA made critical advances in ensuring that the full range of our national preparedness efforts take the unique needs of at-risk populations into consideration—such as children, pregnant women, seniors, and others who may need additional response assistance, in the event of a public health emergency. I know a number of these advances are addressed in strategy and implementation plans released recently.

Dr. Lurie, what are some areas of real progress with regards to at-risk individuals and where do you think further advances are needed?

Answer 1. The Office of the Assistant Secretary for Preparedness and Response (ASPR), in collaboration with the Centers for Medicare & Medicaid Services (CMS), has utilized limited administrative claims data to evaluate the impact of prolonged power outages on health care delivery, and individuals that rely on electricity-dependent medical equipment and health care services. In addition, ASPR and CMS are creating maps to inform and support State and local health department emergency planning and response. Pilot programs in the city of New Orleans and in Broome County, NY successfully demonstrated that limited administrative claims data can be securely disclosed to and used by a health department to rapidly identify and conduct potentially lifesaving outreach to at-risk individuals that live independently and rely upon electricity-dependent oxygen medical devices. Building on these successes, ASPR and CMS are launching the Department of Health and Human Services (HHS) At-Risk Resiliency Initiative that will be comprised of three national data and mapping capabilities that can inform and support all U.S. territories, State, local, and community partners in emergency planning for and/or assisting electricity-dependent at-risk populations. Finally, ASPR is also collaborating with CMS and other partners, to identify medications that may be needed by at-risk populations prior to a disaster and explore mechanisms that can expedite advance or rapid medication refills for those that may need them after a disaster. In addition, ASPR has worked on the following activities to address at-risk populations during disasters:

- Publishing the *2012–2013 Report of the Children's HHS Interagency Leadership on Disasters (CHILD) Working Group*.<sup>3</sup> This report documents the significant progress HHS has made in addressing the needs of children in disasters since 2011 and highlights three new focus areas: pregnant and breast feeding women and newborns, children at heightened risk, and interdepartmental and non-governmental organization collaboration.

<sup>3</sup><http://www.phe.gov/Preparedness/planning/abc/Documents/child-wg-report2012-2013.pdf>.

- Developing the “Guidance on Integrating People with Access and Functional Needs into Disaster Preparedness Planning for States and Local Governments.”
- Developing the “Pediatric Preparedness for Healthcare Coalitions (Part I)” Webinar and Resources, as well as a Part II Webinar.
- Developing the “Disaster Preparedness Planning for Older Adults Web page.”
- Developing “Promising Practices for Communication with Persons with Access and Functional Needs” Webinar with DHS.
- Developing “Disaster Preparedness for Family Caregivers” Webinar.
- Developing the “2014 HHS Human Services Concept of Operations.”
- Launching the HHS Preparedness for Pregnant Women Working Group. The goal of this working group is to integrate the needs of pregnant women across all disaster and public health emergency preparedness, response, and recovery activities. The working group will focus on opportunities to identify, develop, and update tools and resources within HHS including infographics, job aids, and other actionable products that can easily be disseminated and utilized by health care providers, public health practitioners, human services agencies, advocacy groups, and emergency management officials.
- Launching ASPR and the Administration for Community Living Working Group to integrate the Aging Network into Public Health and Medical Response (ESF #8). The goal of this working group is to increase awareness of the Incident Command System and develop tools and training to improve coordination of the Aging Network (long-term care, home and community-based services, meal delivery services, etc.) with ESF #8 and health care coalitions to ensure that the health and medical needs of older adults who may be impacted by public health emergencies and disasters are addressed.
- Publishing the “Disaster Response Guidance for Health Care Providers: Identifying and Understanding the Health Care Needs of Individuals Experiencing Homelessness.” This HHS-led document is part of a larger collaboration with the Department of Veterans Affairs, the Department of Housing and Urban Development, and other Federal partners to develop a Homeless Disaster Planning Toolkit.<sup>4</sup>
- Developing and publishing a website and fact sheet on “Cultural and Linguistic Competency in Disaster Preparedness and Response” and development of the “American Indian & Alaskan Native Disaster Preparedness Resource.”
- Coordinating and leading the Interagency Coordinating Council on Emergency Preparedness and Individuals with Disabilities (ICC) Health Subcommittee to promote the safety, security, and equal access to services for people with disabilities during emergencies.

SENATOR MIKULSKI

*Question 1.* As you know, I authored the provision in the PAHPA Reauthorization that created the HHS National Advisory Committee on Children and Disasters (NACCD). I felt the creation of the NACCD was important because of the continued need to ensure that our Federal disaster preparedness and response programs are adequately addressing the needs of our most vulnerable, children. This year marks 5 years since the National Commission on Children and Disasters issued its final report looking comprehensively at each of our Federal agencies, States, and non-governmental entities to make recommendations for ways each can improve its readiness to meet children’s unique medical and mental health needs during and in the aftermath of a disaster. While much progress has been made, many gaps remain in our level of preparedness for children. We can and should be doing all we can to ensure we as a nation are prepared to meet the needs of children, who represent 25 percent of the population.

I want to commend you for selecting such a distinguished group of experts from inside and outside the Federal Government for the NACCD including its Chair, Dr. Michael Anderson, a pediatric critical care medicine doctor from Cleveland, OH, and Linda MacIntyre, the Chief Nurse at the American Red Cross. I have high hopes and expectations for the NACCD and I look forward to receiving their recommendations and guidance.

Can you tell me how you are utilizing the expertise of the NACCD as HHS, ASPR and CDC respond to outbreaks and threats such as Ebola, Enterovirus D-68, and now measles?

*Answer 1.* The NACCD was tasked with examining the current State of readiness to address the ability of the pediatric healthcare system to surge in the case of an outbreak of an infectious disease. This surge capacity task examines the current state of readiness across the Nation for a surge of pediatric patients in the event

<sup>4</sup>[http://www.vemec.org/assets/1/6/Toolkit\\_Project\\_One-Page.pdf](http://www.vemec.org/assets/1/6/Toolkit_Project_One-Page.pdf).



of an infectious disease outbreak such as influenza, measles, or Enterovirus D-68. Crises such as these could overwhelm local pediatric capabilities and the NACCD has been asked to focus on how health care organizations would cope in the near-term with large numbers of ill or infectious pediatric patients. To date, committee members working on this task have gathered pertinent information from several pediatric health care experts around the country. This includes insight and understanding of the issues concerning pediatric surge capacity as well as local and national readiness gaps for a large number of infectious ill children. The members are synthesizing this information in a report with recommendations for improving pediatric transport, children's and non-children's hospital capacities, as well as tools to strengthen pediatric health care coalitions. The NACCD Surge Capacity Report (*Near-Term Strategies to Improve Pediatric Surge Capacity During Infectious Disease Outbreaks*) was considered at a public meeting on April 30, 2015.<sup>5</sup>

The Health Care Preparedness Task looks across the broad health care system to care for large numbers of ill or injured children in the aftermath of public health threats, medical disasters, and mass-trauma/casualty emergencies. Topic areas that the committee members will examine include the current State of facility preparedness, quality control programs, granting structures, innovation, communication streams, and medical counter measures. The members will propose strategies for mitigating identified gaps and suggest best practices and tools for increasing pediatric health care readiness. Members are finalizing the framework for a report of recommendations, as well as identifying subject matter experts to engage and gather insights that will inform the report's content. The NACCD plans to provide a report of its findings in October 2015.

*Question 2.* Can you describe how you are best utilizing the existing Federal funding mechanisms through the Hospital Preparedness Program (HPP) and the Public Health Emergency Program (PHEP) to ensure grantees are prepared to meet the needs of children?

Answer 2. As aligned cooperative agreements, ASPR's Hospital Preparedness Program (HPP) and CDC's Public Health Emergency Preparedness (PHEP) program include a number of joint and specific program requirements that address the particular needs of at-risk individuals and those with special medical needs, including children, in public health and medical emergencies. Awardees must:

- Complete jurisdictional risk assessments to identify potential hazards, vulnerabilities, and risks within the community, including interjurisdictional (e.g., cross-border) risks that specifically relate to public health, medical, and behavioral health systems and the functional needs of at-risk individuals, including children.
- Conduct an annual public health and medical preparedness exercise or drill that includes the access and functional needs of at-risk individuals, including children. Awardees must also provide a report in the following year's funding application on the strengths and weaknesses identified and corrective actions taken to address material weaknesses. HPP awardees were required to consider the access and functional needs of at-risk individuals, including children, and engage these populations as they planned for Budget Period 4 (July 2015–June 2016) health care coalition-based exercises.
- Maintain updated plans describing activities they will conduct with respect to pandemic influenza as required by Sections 319C-1 and 319C-2 of the Public Health Service Act. This also includes efforts to address the needs of at-risk individuals, including children.
- Describe the structures or processes in place to ensure that access and functional needs of at-risk individuals, including children, are included in public health/health care and behavioral health response strategies and are identified and addressed in operational work plans.
- Obtain public comment and input on public health emergency preparedness and response plans and implementation using existing advisory committees, or similar mechanisms, to ensure continuous input from other State, local, tribal stakeholders, and the general public. This includes those with an understanding of at-risk individuals, including children, and their needs.
- Coordinate emergency preparedness and response with designated educational agencies and lead child care agencies in their jurisdictions.
- Include the "Pediatric Preparedness for Healthcare Coalitions (Part II)" Webinar in Budget Period Four HPP Supporting Documents. This two-part webinar describes resources, partnerships and strategies that HPP Directors and Healthcare Coalitions have implemented to strengthen pediatric components within their jurisdiction's healthcare preparedness capabilities. Topics discussed include Federal pol-

<sup>5</sup>The report can be found at: <http://www.phe.gov/Preparedness/legal/boards/naccd/Pages/recommendations>.

icy and efforts to address the needs of children in disasters; Superstorm Sandy lessons learned; putting the pieces together on pediatric response planning; Los Angeles County pediatric surge plan; and pediatric lessons learned (Alaska Shield/Hale Borealis 2014 National Capstone Exercise).

SENATOR CASEY

*Question 1.* This year is the fifth anniversary of the National Commission on Children and Disasters. What progress has been on the Commission's recommendations from 2010?

*Answer 1.* In February 2015, ASPR published the 2012–2013 Report of the Children's HHS Interagency Leadership on Disasters (CHILD) Working Group.<sup>6</sup> This 82-page report documents the progress HHS has made in addressing the needs of children in disasters since 2011 and highlights three new focus areas: pregnant and breast feeding women and newborns; children at heightened risk; and interdepartmental and non-governmental organization collaboration.

The first chapter of the report provides a descriptive list of departmental activities supported by CHILD Working group member agencies since 2011. All activities are grouped into the following categories: behavioral health; medical countermeasures; child physical health, emergency medical services, and pediatric transport; and child care, child welfare, and human services.

These four categories were created by the 2010–2011 CHILD Working Group members upon careful review of the NCCD's recommendations and internal policy and programmatic initiatives already begun across HHS.

In order to demonstrate continued progress, HHS will continue to monitor and report all HHS activities related to children and disasters. For example, in August 2015, HHS launched a new data call for the 2014–2015 Report of the CHILD Working Group.

*Question 2.* How are BARDA, CDC and FDA working together to ensure smooth transitions of products under development, through FDA review, and into the Strategic National Stockpile?

*Answer 2.* The Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response has transitioned more than 85 medical countermeasure (MCM) candidates for chemical, biological, radiological, and nuclear (CBRN) threats from early development at the National Institutes of Health (NIH), the Department of Defense (DoD), and industry into advanced development toward Food and Drug Administration (FDA) approval and potential acquisition under Project BioShield. Twelve of these MCMs have been purchased since 2005 under Project BioShield and another 12 will become mature enough for purchase by 2018. Four Project BioShield MCMs [Raxibacumab anthrax antitoxin (2012), HBA1 botulinum antitoxin (2013), Neupogen for ARS (2015), and AIG anthrax antitoxin (2015)] have been approved by the FDA under the Animal Rule. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) governance structure includes: Integrated Program Teams, the Enterprise Executive Committee, Enterprise Senior Council oversight bodies, MCM portfolio reviews, a multiyear budget process, joint MCM projects, and monthly meetings between leadership and staff from BARDA, the Centers for Disease Control and Prevention (CDC), and NIH's National Institute of Allergy and Infectious Diseases (NIAID) to ensure continuous coordinated communication and seamless transition among these HHS agencies.

*Question 3.* CDC has ranked CRE and *Clostridium difficile* as urgent antibiotic resistance threats, the highest level of resistance threat, but these organisms are not on PHEMCE's list of high priority threats. How does PHEMCE determine which organisms to include on the list? Should these resistant organisms be added?

*Answer 3.* The PHEMCE addresses high priority threats, determined by the Secretary of Homeland Security, that pose a material threat sufficient to affect national security. This includes a material threat determination (MTD) issued by the Secretary of Homeland Security and/or a threat that PHEMCE leadership has determined has the potential to seriously threaten national health security.

The PHEMCE recognizes the threat posed by naturally occurring and accidental threats to national health security that are outside the realm of the Department of Homeland Security (DHS) threat and risk assessment processes. For example, pandemic influenza was included in the PHEMCE high priority threat list based on PHEMCE leadership's consensus that it posed a serious threat to national health security and warranted investment in targeted MCM-related planning and response.

<sup>6</sup><http://www.phe.gov/Preparedness/planning/abc/Documents/child-wg-report2012-2013.pdf>.

To better standardize the process by which such decisions are made for particular naturally occurring threats, including antibiotic resistant organisms, the PHEMCE is currently developing a risk assessment methodology and process to examine emerging infectious diseases (EIDs). This process, anticipated for completion in fiscal year 2016, will inform PHEMCE leadership decisions on which EID threats require PHEMCE response at the research and development, requirement, advanced research and development, large-scale production, stockpiling, and/or utilization planning levels. While the intention of this framework is to review EIDs, it will be designed in a way that allows for the evaluation of a wide variety of organisms including health care associated infections such as *Clostridium difficile* and CRE.

In the meantime, the PHEMCE will continue efforts to combat drug-resistant bacteria in general. As noted in the 2014 PHEMCE Strategy and Implementation Plan, it is a PHEMCE programmatic priority to support Executive Order 13676, "Combating Antibiotic-Resistant Bacteria," which calls for, among other actions, development of new and next-generation MCMs that target antibiotic-resistant bacteria that present a serious or urgent threat to public health.

*Question 4.* The amount that has been spent on the development of rapid diagnostics is small compared to the antimicrobial development budget. Since there is evidence that we can conserve our antibiotics if we are able to rapidly diagnose an infection, should we focus more resources on the development of rapid diagnostics? What are some of the barriers to the development of rapid diagnostics?

*Answer 4.* BARDA values and supports development in diagnostics for biothreats, radiation exposure (*i.e.*, biodosimetry), influenza, drug-resistant bacteria and viruses, and EIDs. BARDA is currently supporting the development of multiple diagnostic candidates in these areas: four for biothreats (*e.g.*, anthrax); five for biodosimetry; four for influenza and antiviral drug resistance; and one for Ebola. In fiscal year 2016, as funds become available, BARDA plans to add diagnostic candidates for antimicrobial drug resistance. BARDA's support focuses on rapid diagnostics for point-of-care throughout institutional usage. BARDA partners with CDC to set strategic diagnostic goals and plans, and to support development for many of these diagnostic candidates. Thus far, BARDA support has led to FDA clearance and marketing of five diagnostic assays for detection of influenza.

Primary barriers to the development of rapid diagnostics for pathogenic bacteria include the following:

- poor clinical sample collection methods;
- availability of validated reference reagents and samples;
- assays with high enough specificity for reliable and reproducible clinical diagnoses;
- acceptance and widespread usage by the medical community; and
- limited commercial marketplace.

*Question 5a.* I understand that HHS is working with the Department of Homeland Security to conduct a reassessment of certain material threat assessments and, by extension, the medical countermeasures requirements for threats such as anthrax and smallpox.

Could you please provide a timeline of this threat reassessment process?

*Answer 5a.* On January 20, 2004, the Department of Homeland Security (DHS) issued a Material Threat Determination (MTD for *Bacillus anthracis* (anthrax). Subsequently, Material Threat Assessment (MTA) 1.0 for Anthrax was published in April 2005.

On September 23, 2004, DHS issued a MTD for smallpox. The most recent Smallpox MTA was published February 2012.

MTA 2.0 for Anthrax began fall of 2013 with the development of a working group comprised of interagency subject matter experts to frame the approach. Modeling efforts began August 2014. While weather selection, indoor transit, and integrated modeling efforts have already concluded, outdoor modeling, Intelligence Community elicitation, and development of the illustrative scenario matrix are concurrent activities. A draft report for MTA 2.0 is expected to be ready for HHS review by July 2015 with finalization by the end of 2015.

Upon receipt, BARDA's modeling unit will utilize these assessments (anthrax being the first threat for analysis), develop scenario-based computer models on the medical consequences of these threats, and determine their impacts relative to non-medical and MCM interventions. Results from these analyses will inform PHEMCE product-specific requirements, MCM development, and product procurement for stockpiles.

Discussions focused on prioritization and planning for future MTA efforts are ongoing.

*Question 5b.* When do you expect this process to be complete?

Answer 5b. DHS draft MTA 2.0 became available in July 2015 for HHS review for anthrax medical consequence modeling and analysis. The final version should be completed by the end of 2015. Others like smallpox, ionizing radiation, and chemical agents will follow upon receipt of MTAs from DHS.

*Question 5c.* Would these reassessments have the potential to change BARDA's plans for anthrax and smallpox MCM advanced research and development or stock-piling?

Answer 5c. Potentially, the MTAs may change and thus impact development and procurement of CBRN MCMs by PHEMCE partners at NIAID, BARDA, and CDC.

SENATOR FRANKEN

*Question.* When news of the Ebola outbreak spread, hospitals in Minnesota responded quickly and took key steps to ensure that they were prepared to screen, diagnose, and treat affected patients. These hospitals incurred significant expenses for things like personal protective equipment and staff training—most of which they have not been compensated for up to this point. Congress provided HHS with the authority to use Ebola emergency funding to reimburse hospitals directly for care that they provided to Ebola patients.

Given all the resources that hospitals in Minnesota and elsewhere expended to make sure that they were prepared to treat Ebola patients, my question is, how you are determining eligibility for reimbursement under this authority?

Answer. The Hospital Preparedness Program (HPP) provided \$162 million in Ebola preparedness and response funds through a funding formula to all HPP awardees in May 2015. These awardees are the public health departments in all 50 States, DC, select metropolitan jurisdictions (Chicago, Los Angeles County, and New York City), U.S. territories, and freely associated States. The majority of the funds will be further sub-awarded to support health care facilities that are capable of serving as Ebola treatment centers and assessment hospitals for their States or jurisdictions. The funding will also support health care coalitions prepare frontline hospitals, emergency medical services agencies, and the overall health care system. The funding formula for the HPP Ebola FOA takes into account Ebola risk, which is based on the travel patterns of individuals coming from the affected countries. It also reflects West African diaspora population centers and jurisdictions with enhanced airport entrance screenings to ensure that the States and localities most likely to have a case of Ebola are fully prepared. As a high risk State for Ebola, Minnesota's allocation was among the largest at \$5,513,716. Hospitals designated as Ebola treatment centers by State health officials as of February 14, 2015 will receive no less than \$500,000 through this FOA, including four in Minnesota: Allina Health's Unity Hospital, Fridley, MN; Children's Hospitals and Clinics of Minnesota—St. Paul Campus, St. Paul, MN; Mayo Clinic Hospital—Rochester, St. Mary's Campus, Rochester, MN; and University of Minnesota Medical Center, West Bank Campus, Minneapolis, MN.

State awardees have the discretion to provide additional funding to the Ebola treatment centers as their allocation allows.

In addition, nine State or local health departments, along with their health facility partners, were awarded funding on June 12, 2015 to establish regional Ebola and other special pathogen treatment centers (1 in 9 of the 10 HHS regions). As necessary, these centers can be ready within a few hours to receive a confirmed Ebola patient from their region, across the United States, or medically evacuated from outside of the United States. These hospitals will also have enhanced capacity to care for other highly infectious diseases. The Minnesota Department of Health, in partnership with the University of Minnesota Medical Center, Minneapolis, MN, was one of the recipients of these competitively awarded funds, to serve as the regional Ebola and other special pathogen treatment center for HHS Region Five. Funding will be distributed to these awardees incrementally over the full 5-year project period in order to sustain and maintain readiness for Ebola and other highly pathogenic infectious diseases. The total funding to establish regional Ebola and special pathogen treatment centers across the country is \$32.5 million.

Awardees can use their discretion when providing supplemental funds to sub-recipient health care facilities and coalitions for previous Ebola preparedness costs incurred since July 2014. However, awards may not be used to reimburse health care facilities for direct patient treatment costs. HPP seeks to build capabilities within the entire health care system to better prepare communities for future outbreaks of Ebola and other novel, highly pathogenic diseases.

The office of the Assistant Secretary for Preparedness and Response (ASPR) has established a program to reimburse hospitals and other health care providers for di-

rect and uncompensated treatment and domestic transportation costs accrued while caring for a confirmed Ebola patient in the United States. This program reimburses care provided to patients treated since the start of the Ebola response and remain in place should additional patients require treatment during the 5-year funding period, as set forth in the Consolidated and Further Continuing Appropriations Act, 2015. Health care facilities began submitting claims on April 15.

SENATOR BALDWIN

In the House of Representatives, I worked to include language in the Pandemic All-Hazards Preparedness Reauthorization Act of 2013 that added the critical care system to the Federal Government's medical preparedness and surge capacity goals to ensure that critical care is included in emergency planning efforts. I also recently introduced the bipartisan Critical Care Assessment and Improvement Act to evaluate our critical care infrastructure, as the recent Ebola outbreak and severe flu season has underscored the importance of critical care systems.

*Question 1.* Dr. Lurie, what methods are currently being used by the Department of Health and Human Services to identify and deploy surge medical providers with critical care expertise, like intensivists, nurses and respiratory therapists, as well as those that are able to care for children and infants in need of critical care?

*Answer 1.* The Office of the Assistant Secretary for Preparedness and Response (ASPR), in collaboration with the Centers for Medicare & Medicaid Services (CMS), has utilized limited administrative claims data to evaluate the impact of prolonged power outages on health care delivery, and individuals that rely on electricity-dependent medical equipment and health care services, such as dialysis. Following Hurricane Sandy, dialysis studies have allowed us to see how dialysis-dependent Medicare beneficiaries were adversely impacted and have identified clinical preparedness practices which can help us better anticipate, plan for, and respond to needs in a disaster.<sup>7</sup> For example, our studies provided evidence that Medicare dialysis-dependent patients who received early dialysis in anticipation of Sandy's landfall had their odds of an emergency department visit reduced by 20 percent, hospitalization in the week of the storm reduced by 21 percent, and 30-day mortality reduced by 28 percent.<sup>8</sup> ASPR, in collaboration with CMS, is actively disseminating these important findings across the dialysis community as well as encouraging healthcare and public health officials to encourage and prioritize early dialysis, where appropriate, in advance of a notice emergency such as a hurricane or blizzard.

ASPR and CMS have also established the HHS emPOWER Initiative, a data and mapping collaboration to help inform and support Federal, State, local, and community emergency planning and response activities for those in need of electricity-dependent medical and assistive equipment and oxygen, home health, and dialysis healthcare services. This information is made available to State and local health departments and the community partners and appropriately balances the need to support emergency planning and response with the need to protect privacy. One component is the HHS emPOWER Map,<sup>9</sup> a publicly available and interactive map that provides de-identified and aggregated population data down to the zip code level for Medicare beneficiaries that rely upon electricity-dependent medical and assistive equipment. Another component provides State and local health public health authorities with more de-identified and granular data (*e.g.*, type of medical equipment, home health services, oxygen-tank use, dialysis-dependence) that can support more detailed emergency planning and response activities. Public health authorities that meet certain Health Insurance Portability and Accountability Act requirements can also request secure access to more detailed information, such as addresses, to facilitate life-saving assistance and outreach as part of an emergency response. Finally, ASPR is also collaborating with CMS and other partners, to identify medications that may be needed by at-risk populations prior to a disaster and explore mechanisms that can expedite advance or rapid medication refills for those that may need them after a disaster.

Specific activities include:

- Publishing the *2012–2013 Report of the Children's HHS Interagency Leadership on Disasters (CHILD) Working Group*.<sup>10</sup> This 82-page report documents the significant progress HHS has made in addressing the needs of children in disasters since 2011 and highlights three new focus areas: pregnant and breast feeding women and

<sup>7</sup> <http://www.ncbi.nlm.nih.gov/pubmed/25156306>.

<sup>8</sup> <http://www.ncbi.nlm.nih.gov/pubmed/26120039>.

<sup>9</sup> <http://www.phe.gov/empowermap/>.

<sup>10</sup> <http://www.phe.gov/Preparedness/planning/abc/Documents/child-wg-report2012-2013.pdf>.

newborns, children at heightened risk, and interdepartmental and non-governmental organization collaboration. A comprehensive summary of HHS activities related to medical countermeasures, child physical health, emergency medical services, and pediatric transport is found on pages 11 through 20 of the report.

- Developing the “Pediatric Preparedness for Healthcare Coalitions (Part I)” Webinar and Resources, as well as a Part II Webinar.

*Question 2.* In response to the Ebola outbreak last year, Wisconsin designated three Wisconsin health systems to care for patients who may be diagnosed with the Ebola virus. These hospitals have invested a significant amount of staff and financial resources to ensure that they are ready to provide the best and safest care in the event that Wisconsin must care for a patient with Ebola. It is critical that our Federal efforts support these important investments.

How much of the \$162 million in emergency funding being provided to States for Ebola preparedness will be provided directly to hospitals, and how will such funds prioritize State-designated treatment centers, such as the three in Wisconsin?

*Answer 2.* The Hospital Preparedness Program (HPP) provided \$162 million in Ebola funding through a funding formula to all HPP awardees in May 2015. These awardees are in all 50 States, DC, select metropolitan jurisdictions (Chicago, Los Angeles County, and New York City), U.S. territories, and freely associated States to support health care facilities that are capable of serving as Ebola treatment centers and assessment hospitals for their States or jurisdictions. The funding will also support health care coalitions (HCCs) to prepare frontline hospitals, emergency medical services agencies, and the overall health care system.

Awardees must limit their direct costs (excluding sub-awards to HCCs and health care facilities) to no more than 10 percent of their allocation. Of the funds for sub-awards:

- At least 30 percent must be allocated to health care coalitions in the jurisdiction (Wisconsin has eight health care coalitions across the State).
- No more than 70 percent may be used to provide funding directly to Ebola treatment centers and/or assessment hospitals.

Hospitals that have been designated by State health officials as Ebola treatment centers as of February 14, 2015 will receive no less than \$500,000 through the HPP awards, including three in Wisconsin: UW Health—University of Wisconsin Hospital, Madison and the American Family Children’s Hospital, Madison, WI; Froedtert and the Medical College of Wisconsin—Froedtert Hospital, Milwaukee, WI; and Children’s Hospital of Wisconsin, Milwaukee, WI. States and awardees have the discretion to provide additional funding to the Ebola treatment centers as their allocation allows.

SENATOR WARREN

*Question 1a.* The Ebola outbreak in West Africa has raised questions about whose responsibility it is to lead, coordinate, and finance international infectious disease response efforts, especially when local governments are ill-equipped to handle a crisis alone. There are many international groups, including the World Health Organization, non-governmental organizations like the Gates Foundation and Doctors Without Borders, and initiatives like the Global Health Security Agenda which brings together U.S. Government agencies and partner nations to make strategic investments to develop a better system of preventing, detecting, and responding to disease threats worldwide.

Who do you think is ultimately responsible for the coordinating and financing international outbreak response efforts?

*Answer 1a. International-Level Coordination.*—The United Nations (UN) Cluster Approach was established in June 1992 by the U.N. Inter-Agency Standing Committee to strengthen humanitarian assistance during complex, multi-sectoral responses. More specifically, it strengthens response to situations where humanitarian needs are of sufficient scale and complexity and require the coordination and engagement of a wide range of international stakeholders. Within the U.N. Cluster Approach, the World Health Organization (WHO) leads the Health Cluster and has the ultimate responsibility for coordinating response efforts to international emergencies with a public health component, including efforts among WHO Member States, other U.N. Agencies, and non-governmental organizations.

Additionally, WHO has a leading role under the 2005 International Health Regulations (IHR), which includes determining whether particular events constitute a public health emergency of international concern (PHEIC). Other WHO responsibilities include disseminating information to State Parties, building and strengthening core public health capacities for surveillance and response to PHEIC, developing

and recommending measures for surveillance, and the prevention and control of public health emergencies of international concern. WHO's leading role in emergencies was strengthened by Article 2(d) of WHO's Constitution and World Health Assembly Resolutions 34.26, 46.6, 48.2, 58.1, 59.22, 64.10, and 65.20.

WHO has also established an Emergency Response Framework<sup>11</sup> and a Global Emergency Management Team to provide overall policy, strategy, and management guidance. This is important to coordinate an effective health sector response as the Health Cluster Lead Agency and in line with responsibilities under the 2005 IHR. In this role, WHO has the responsibility for coordinating global financing and resources contributed to public health responses (direct funding and in kind support). A proposal to establish a contingency fund to support public health emergency responses will be considered by the Sixty-eighth World Health Assembly. When this happens, the WHO Director-General will be asked about options regarding the size, scope, sustainability, operations and sources of financing for such a fund. In addition, the Director-General will be asked about accountability mechanisms including possible internal sources of funding from within WHO's existing program budget. This is done taking into account other relevant financing mechanisms and emergency funds already in operation or being considered, at regional and global levels.

In addition to HHS's full support of the implementation of the IHR (2005) through numerous public health emergency and response capacity building arrangements and public health activities internationally, HHS participates in a number of specific international partnerships that serve to strengthen global capacity to prevent, detect, respond, and recover from international public health emergencies, as well as to foster technical and policy coordination among key stakeholders prior to and during a response. Among others, these partnerships include the Global Health Security Agenda, the Global Health Security Initiative (which consists of the G7 countries, Mexico, and the European Commission, as well as the WHO as an expert advisor), the North American Plan for Animal and Pandemic Influenza (NAPAPI), and the United States-Canada Beyond the Border Initiative.

*U.S.-Government-Level Coordination.*—In accordance with the Presidential Policy Directive (PPD)–1 process for coordinating executive departments and agencies as they develop, integrate, and implement national security policy, the National Security Council (NSC) typically convenes Interagency Policy Committees as the U.S. Government-wide policy coordination structure. This is done to support the response to public health emergencies. A number of recent frameworks were recently developed to coordinate the provision of international assistance in response to international emergencies that pose a risk to the United States including for chemical, biological, radiological, and nuclear (CBRN) incidents, and pandemic influenza. These frameworks specifically address the deployment of medical countermeasures and personnel in response to a request for assistance from another government or the WHO/international organizational. However, no U.S. Government policy framework outlines the respective roles and responsibilities of U.S. Government departments and agencies in response to public health events of international concern that require full-spectrum public health intervention (*i.e.*, epidemiologic investigation, healthcare services, risk communication, community coordination, environmental services and international border controls) to prevent regional and global spread.

The National Response Framework establishes the U.S. Department of Health and Human Services (HHS) as the leader for coordinating response to domestic public health and medical emergencies under Emergency Support Function #8 (ESF–8). Within HHS, the Pandemic and All-Hazards Preparedness Act (PAHPA) provides the Assistant Secretary for Preparedness and Response (ASPR) with a mandate to “provide leadership in international programs, initiatives, and policies that deal with public health and medical emergency preparedness and response.” Additionally, other U.S. agencies, such as the U.S. Agency for International Development and the Department of Defense, have legal authorities and funding to lead, coordinate, or implement international assistance and disaster response. However, there is no overarching U.S. Government coordination framework that describes the roles, responsibilities, or the legal and funding authorities of all relevant U.S. Government stakeholders during such an international response with potential domestic implications not covered by a Stafford Act declaration.

*Question 1b.* What changes need to occur to empower such a system?

*Answer 1b. International-Level Coordination.*—Based on lessons learned from the Ebola response, efforts are underway to strengthen global preparedness and ensure that WHO has the capacity to prepare for and respond to future large-scale outbreaks and health emergencies. Accordingly, a number of reform proposals were

<sup>11</sup> [http://www.who.int/hac/about/erf\\_.pdf](http://www.who.int/hac/about/erf_.pdf).

brought before and adopted by the Sixty-eighth World Health Assembly in May 2015. Areas of focus include reaffirming WHO's role and leadership as the Global Health Cluster Lead Agency, improving surveillance and information sharing, calling for WHO and Member States to further efforts to strengthen health systems establish capacities for public health preparedness and response under the 2005 IHR, establishing mechanisms for rapid medical assistance (including establishment and deployment of foreign medical teams), and strengthening efforts to ensure access to drugs and vaccines and developing a WHO-managed \$100-million contingency fund to provide financing for in-field operations for up to 3 months.

*U.S. Government-Level Coordination.*—The USG should consider the development of a generic USG-wide framework that contemplates a variety of scenarios and describes the roles, responsibilities, funding, and legal authorities of relevant stakeholders during the different phases of a response to public health and medical emergencies with a domestic-international interface. This framework should include triggers allowing responsibilities and leadership to shift from one U.S. Department or Agency to another depending on their specific mission and authorities. This includes events caused by CBRN threats, pandemic influenza, emerging or re-emerging infectious diseases, and natural disasters that originate abroad but potentially impact U.S. national health security.

Under the role and authorities given to ASPR by PAHPRA, ASPR, in collaboration with key HHS stakeholders, should also develop an overarching HHS framework for responding to public health emergencies with a domestic-international interface. The Framework should highlight the leading role of HHS and specifically ASPR in coordinating the public-health aspects of emergencies abroad that can have an impact in U.S. health security. It should also clarify the roles and responsibilities of the different HHS offices during a response and (*e.g.*, CDC, NIH, FDA) align these roles with existing roles during domestic responses.

*Question 2.* In order for the United States to have the capacity to respond to outbreaks at home and abroad, we need to have individuals who are trained and experienced in handling infectious agents. Biosafety training programs are essential to prepare both governmental and nongovernmental personnel to effectively respond to epidemics. Do ASPR and CDC currently, or have plans to, leverage nongovernment physicians and researchers, capabilities, and infrastructure to enhance the Nation's clinical and research capacities for future outbreaks?

*Answer 2.* To reduce cost and save time in product development and manufacturing, the Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response (ASPR) has established a National Medical Countermeasure Response Infrastructure comprised of core service assistance programs to assist product developers on a daily basis while ensuring rapid and nimble response in a public health emergency. BARDA has employed this medical countermeasure (MCM) infrastructure for development of CBRN MCMs on a routine basis and is now utilizing them in the current Ebola response by supporting the development and manufacturing of several Ebola therapeutics and vaccines. BARDA's Nonclinical Studies Network (NCSN), which was established in 2010 and is composed of 17 high-biocontainment laboratories in the United States and the United Kingdom, has developed qualified animal models for CBRN threats, performed animal challenge studies for CBRN MCMs, and evaluated potential CBRN MCM candidates in these animal models prior to BARDA investment. Today, the NCSN is conducting critical animal challenge studies for promising Ebola monoclonal and antiviral drug therapeutic candidates.

BARDA's three Centers for Innovation in Advanced Development and Manufacturing are helping to develop anthrax vaccines and are expanding the production of new and existing Ebola monoclonal antibodies similar to ZMapp in mammalian cells. BARDA's Fill Finish Manufacturing Network, established in 2013 with four Contract Manufacturing Organizations having aseptic filling capabilities in the United States, is now being used to formulate and fill multiple Ebola antibody and vaccine candidates into vials for clinical efficacy studies in West Africa. Two Contract Research Organizations among the five members of BARDA's Clinical Studies Network are working with BARDA scientists and CDC to conduct Ebola vaccine clinical trials in Sierra Leone. BARDA's modeling unit, which routinely provides medical consequence modeling of CBRN threats to inform MCM requirements, generated key models and forecasts on the impacts of MCM intervention on the epidemiology of the 2009 H1N1 pandemic, 2013 H7N9 outbreaks, and of the current Ebola epidemic in West Africa. All together, these programs constitute an active and seasoned infrastructure able to respond to known and unknown emerging infectious diseases. BARDA investments to our national MCM infrastructure since 2010 have played a major role in our national response to the current Ebola epidemic. More-



over, these investments will become even more vital for MCM response to public health and national security emergencies in the coming years.

In 2012, ASPR established a science preparedness initiative to develop a framework for the integration of scientific research and to mobilize clinical and scientific research responders during HHS disaster-response efforts.<sup>12</sup> Once fully developed, the science preparedness framework will include a network of pre-identified scientists, including those with expertise in biosafety, applied biosafety research, and infection control training, who can rapidly initiate research in response to all hazards. The framework will also establish procedures for rapid institutional review of clinical research involving human subjects, and the development of pre-scripted clinical and scientific research protocols.

ASPR is also managing the S3 (Science, Safety, and Security) program, which addresses biosafety, biosecurity, biocontainment, and bio-risk management. The S3 program promotes transparency and broader awareness about the evolving nature of biological agents that can be hazardous and instructs how to handle and use these agents safely and securely. Resources provided on the program's website<sup>13</sup> are directed toward laboratory personnel who work with potentially hazardous biological agents, their supervisors, management personnel at their institutions of employment, policymakers, and the public.

Recognizing a need to prepare the U.S. health care system to safely assess and care for patients with suspected and confirmed cases of Ebola, ASPR and CDC jointly awarded \$12 million on July 1, 2015, to establish a National Ebola Training and Education Center (NETEC). While the focus of this funding is on preparedness for Ebola, as required in the appropriations language, it is likely that preparedness for other novel, highly pathogenic diseases will also be enhanced through these activities. The NETEC is a consortium of all three U.S. hospitals that successfully and safely treated patients with Ebola: Emory University in Atlanta, GA; University of Nebraska Medical Center/Nebraska Medicine in Omaha, NE; and Bellevue Hospital Center in New York, NY. NETEC will offer expertise, training, technical assistance, peer review, monitoring, and recognition, to State health departments, regional Ebola and other special pathogen treatment centers, State and jurisdiction-based Ebola treatment centers, and assessment hospitals. However, recipients may not use funds for research or clinical care.

More specifically, NETEC will build a comprehensive set of activities and deliverables for public health departments, U.S. health care providers, and facilities to safely and successfully identify, isolate, assess, transport, and treat patients with Ebola, or persons under investigation for Ebola. In addition, it will develop and lead a national peer review and recognition program for the regional Ebola and other special pathogen treatment centers. Throughout the 5-year project period, NETEC will modify materials developed (*e.g.*, curricula and templates) as the Ebola outbreak evolves and the science advances.

NETEC will develop metrics to measure facility and health care worker readiness (including health care worker training). Using these metrics, NETEC will conduct peer review assessments, monitoring, and recognition reporting. These metrics should complement and build from the capabilities detailed in CDC's *Interim Guidance for Hospital Preparedness*, and other additional capabilities necessary for NETEC. Regional Ebola and other special pathogen treatment centers will be assessed annually while the State and jurisdiction Ebola treatment centers and assessment hospitals will be assessed as mutually agreeable over the 5-year project period. ASPR and CDC will assist NETEC with prioritizing requests from health departments and hospitals, in the event that requests are unmanageable. In order to address gaps, NETEC will provide HHS with detailed reports concerning each facility's assessment results, including a summary of all NETEC-provided assistance.

NETEC will develop a training curriculum and will continuously update a comprehensive set of educational materials, resources, and tools to build and maintain health care worker readiness for Ebola-virus diseases and other novel, highly pathogenic diseases. Under this capacity, NETEC will focus on the knowledge, skills, and abilities needed to safely and successfully identify, isolate, assess, transport, and clinically treat a suspected Ebola patient in accordance with U.S. Government guidelines.

More specifically, NETEC will provide technical support to train staff at public health departments and health care workers at regional Ebola and other special pathogen treatment centers, State and jurisdiction designated treatment centers, and assessment hospitals. The NETEC will facilitate the planning and observation

<sup>12</sup><http://www.phe.gov/Preparedness/planning/science>.

<sup>13</sup><http://www.phe.gov/s3>.

of facility and regionally based exercises through a variety of methods, including but not limited to:

- Full immersion training at the NETEC or requesting facility location;
- Exercises at an NETEC or requesting facility location on a regular basis (*e.g.*, annually);
- Clinical consults and technical assistance via secure video or telemedicine information technology;
- Onsite and virtual clinical simulation training; and
- Subject matter expert technical assistance visits (*e.g.*, conference calls, webinars), training courses, and exercise templates.

[Whereupon, at 11:57 a.m., the hearing was adjourned.]

